

23
No. 12483

United States
Court of Appeals
for the Ninth Circuit.

ALBERTY FOOD PRODUCTS CO., a Copartner-
ship consisting of ADA J. ALBERTY,
HARRY R. ALBERTY, HELEN M. AL-
BERTY HACKWORTH, KENNETH J.
HACKWORTH, FLORENCE M. ALBERTY
ST. CLAIR and MARGARET M. ALBERTY
QUINN,

Appellant,

vs.

UNITED STATES OF AMERICA,

Appellee.

Apostles on Appeal

Appeal from the United States District Court
Northern District of California,
Southern Division.

No. 12483

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[Clerk's Note: When deemed likely to be of an important nature, errors or doubtful matters appearing in the original certified record are printed literally in italic; and, likewise, cancelled matter appearing in the original certified record is printed and cancelled herein accordingly. When possible, an omission from the text is indicated by printing in italic the two words between which the omission seems to occur.]

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NAMES AND ADDRESSES OF ATTORNEYS

HAUERKEN and

ST. CLAIR,

235 Montgomery Street,
San Francisco, California,

Proctors for Claimant and Appellant.

FRANK J. HENNESSY,

United States Attorney,

Northern District of California,

Post Office Building,

San Francisco, California,

Proctor for Libelant and Appellee.

In the District Court of the United States
For the District of Colorado

Civil 2110

THE UNITED STATES OF AMERICA,
Libelant,

vs.

33 BOTTLES, MORE OR LESS, OF AN ARTICLE
LABELED IN PART "RI-CO TABLETS
HOMEOPATHIC COMBINATION
APP. 275 TABLETS"

LIBEL OF INFORMATION

To the Honorable Judge of the District Court for
the District of Colorado:

Now comes the United States of America by
Thomas J. Morrissey, United States Attorney for
the District of Colorado, and shows to the Court:

1. That this libel is filed by the United States of
America and prays seizure and condemnation of
a certain article of drug, as hereinafter set forth,
in accordance with the Federal Food, Drug and
Cosmetic Act (21 U.S.C. 301 et seq.).

2. That the Alberty Food Products shipped in
interstate commerce from Hollywood, California,
to and into the City and County of Denver, in the
State and District of Colorado, and within the juris-
diction of this Court, via Pacific Intermountain Ex-
press Company, on or about the 25th day of Novem-

ber, A.D. 1946, an article of drug consisting of 33 bottles, more or less, of an article labeled in part:

(bottle) "RI-CO Tablets
Homeopathic Combination
App. 275 Tablets
Each Tablet Contains:
Lithium Benzoicum, Ammonium Phos.
Lycopodium
Mfg. for and Packed by
Alberty Food Prod.
Hollywood, Calif.

Directions: Take tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed."

3. That the aforesaid article is in the possession of Leeds Health House, Denver, Colorado, or elsewhere within the jurisdiction of this Court.

4. That the aforesaid article was misbranded in interstate commerce, within the meaning of the Federal Foods, Drug and Cosmetic Act, 21 U.S.C., Section 352(f) (1) in that its labeling fails to bear adequate directions for use since the only direction appearing in the labeling, namely, "Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed," does not indicate the purpose or condition for which the article is intended and therefore is not adequate for its intelligent and effective use.

5. That the aforesaid article, misbranded in in-

terstate commerce, is subject to seizure and condemnation under 21 U.S.C., Section 334.

Wherefore, Libellant prays that process in due form of law according to the course of this Honorable Court in cases of admiralty jurisdiction issue against the aforesaid article; that all persons having any interest therein be cited to appear herein and answer the aforesaid premises; that this Court decree the condemnation of the aforesaid article and grant libellant the costs of this proceeding against the claimant of the aforesaid article; that the aforesaid article be disposed of as this Court may direct pursuant to the provisions of said Act; and that libelant may have such other and further relief as the case may require.

January, 1947.

UNITED STATES OF
AMERICA,

By /s/ THOMAS J. MORRISSEY,
U. S. Attorney for the
District of Colorado.

Duly verified.

[Endorsed]: Filed January 8, 1947, U.S.D.C.,
District of Colorado.

[Endorsed]: Filed March 7, 1947, U.S.D.C.,
Northern District of California, Southern Division.

[Title of District Court and Cause.]

ORDER FOR WARRANT OF ARREST
AND WRIT OF MONITION

On Application of Thomas J. Morrissey, United States Attorney for the District of Colorado, appearing for the libellant herein, It Is Ordered that a warrant of arrest and writ of monition issue herein, directed to the Marshal of this District, to seize and take into his custody the goods described in the libel herein.

It Is Further Ordered that the Marshal keep same in his custody until the further order of this Court, or the Judge hereof; that he serve a copy of the warrant of arrest and writ of monition upon the person in whose possession he may find said goods, and give notice of such seizure and libel to all persons having, or pretending to have, any right, title or interest in or to said goods, or having anything to say why said Court should not pronounce judgment against said goods, to be and appear before said Court in the courtroom of said Court, at the City and County of Denver, in the State of Colorado, on the 3rd day of March, A.D. 1947 (if it be a court day, or else on the next court day thereafter), at 10 o'clock in the forenoon of said day, then and there to interpose any claim for the same, and to make their allegations in that behalf; that said notice be given by publication in a newspaper of general circulation in said District

of Colorado, for not less than three weeks prior to said 3rd day of March, A.D. 1947.

Done in open Court this 8th day of January, A.D. 1947.

/s/ J. FOSTER SYMES,
District Judge.

[Endorsed]: Filed January 8, 1947, U.S.D.C., District of Colorado.

[Endorsed]: Filed March 7, 1947, U.S.D.C., Northern District of California, Southern Division.

[Title of District Court and Cause.]

WARRANT OF ARREST
AND WRIT OF MONITION

The President of the United States of America:
To the Marshal of the District of Colorado, Greeting:

Whereas, a libel in rem has been filed in the District Court of the United States for the District of Colorado, against 33 bottles, more or less, of an article labeled in part:

(bottle) "RI-CO Tablets
Homeopathic Combination
App. 275 Tablets
Each Tablet Contains:
Lithium Benzoicum, Ammonium Phos.
Lycopodium

Mfg. for and Packed by
Alberty Food Prod.
Hollywood, Calif.

Directions: Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed.”

praying for the usual process of arrest and monition of said Court, and that all persons interested in said goods may be cited to appear and answer in the premises, and that said goods may, for the causes in said libel mentioned, be seized, condemned and confiscated.

You Are, Therefore, Commanded to attach said goods and retain same in your custody until the further order of this Court, or the Judge thereof, respecting the same; and to serve a copy of this writ and give notice to all persons having or pretending to have any right, title or interest in said goods, or having anything to say why the Court should not pronounce judgment against the same, according to the prayer of the libel, that they be and appear before said Court to be held at the City and County of Denver, in the State and District of Colorado, on the 3rd day of March, A.D. 1947 (if it be a Court day, or else on the next Court day thereafter), at 10 o'clock in the forenoon of said day, then and there to interpose any claim for the same, and to make their allegations in that behalf, and that notice be given by publication once a week in the Denver Democrat, a newspaper of general

circulation, published at Denver, Colorado, for three consecutive weeks prior to said March 3, 1947.

And what you shall have taken in the premises, and what you may do, do you then and there make return of, together with this writ.

Witness, the Honorable J. Foster Symes, Judge of the District Court of the United States for the District of Colorado and the seal of said Court at Denver, in said District, this 8th day of January, A.D. 1947.

/s/ G. WALTER BOWMAN,
Clerk of the U. S.
District Court,

[Seal] By /s/ WILLIAM GRAF,
Deputy Clerk.

Marshal's Return

United States of America,
District of Colorado—ss:

I hereby certify and return that I have duly executed the within writ at Denver, in said District, on the 10th day of January, A.D. 1947, by seizing and taking into my custody eight (8) bottles of an article labeled in part "RI-CO Tablets Homeopathic Combination App. 275 tablets," therein described, and now have the same in my possession, subject to the further order of this court.

I also certify and return that I have duly served this writ upon Leeds Health House, from which organization said goods were seized, by handing

to and leaving a true and correct copy thereof with Helen J. Olson, one of the co-partners, at Denver, in said District, on the 10th day of January, A.D. 1947.

And I further certify that due notice of attachment has been given by posting and is being published, as herein provided.

MAURICE T. SMITH,
U. S. Marshal,

By /s/ D. T. POTTER,
Deputy.

Receipt of copy attached.

[Endorsed]: Filed February 6, 1947, U.S.D.C., District of Colorado.

[Endorsed]: Filed March 7, 1947, U.S.D.C., Northern District of California, Southern Division.

[Title of District Court and Cause.]

STIPULATION FOR CHANGE OF VENUE

It Is Hereby Stipulated by and between the United States of America, by Thomas J. Morrissey, United States Attorney for the District of Colorado, and Alberty Food Products Co., a copartnership, consisting of Ada J. Alberty, Harry R. Alberty, Helen M. Alberty Hackworth, Kenneth J. Hackworth, Florence M. Alberty St. Clair and Margaret M. Alberty Quinn, shipper of the product mentioned

in the Libel of Information on file herein, by Hauerken Ames & St. Clair, its attorneys, that the above-entitled cause may be transferred to the District Court of the United States for the Northern District of California, Southern Division.

Dated this 26th day of February, 1947.

/s/ THOMAS J. MORRISSEY,
HAUERKEN, AMES &
ST. CLAIR,

By /s/ GEORGE H. HAUKERKEN,
Attorneys for Alberty Food Products Co., a co-
partnership consisting of Ada J. Alberty,
Harry R. Alberty, Helen M. Alberty Hack-
worth, Kenneth J. Hackworth, Florence M. Al-
berty St. Clair and Margaret M. Alberty Quinn.

[Endorsed]: Filed February 28, 1947, U.S.D.C.,
District of Colorado.

[Endorsed]: Filed March 7, 1947, U.S.D.C.,
Northern District of California, Southern Division.

[Title of District Court and Cause.]

ORDER FOR CHANGE OF VENUE

Upon reading and filing the stipulation for change of venue in the above-entitled proceeding, and good cause therefor appearing;

It Is Hereby Ordered that the above-entitled proceeding be, and the same is hereby, transferred to the District Court of the United States for the Northern District of California, Southern Division.

Dated this 28th day of February, 1947.

/s/ J. FOSTER SYMES,
Judge of the District Court.

A true copy—

Teste:

G. WALTER BOWMAN,
Clerk,

By /s/ WILLIAM GRAF,
Deputy Clerk.

[Endorsed]: Filed March 7, 1947.

[Title of District Court and Cause.]

MONITION

In obedience to a Warrant of Seizure to me directed, in the above-entitled cause, I have seized and taken into my possession the following-described property, to wit: 8 bottles of an article

label in part "RI-CO Tablets Homeopathic Combination App. 275 Tablets." For the causes set forth in the libel now pending in the U. S. District Court for the District of Colorado, at Denver. I hereby give notice to all persons claiming the said described property, or knowing or having anything to say why the same should not be condemned and forfeited, and the proceeds thereof distributed according to the prayer of the libel, that they be and appear before the said Court, to be held in and for the District of Colorado, at the United States Court Room, in the City of Denver on the 3rd day of March, 1947, at 10 o'clock on the forenoon of that day, if the same shall be a day of jurisdiction, otherwise on the next day of jurisdiction thereafter, then and there to interpose a claim for the same, and to make their allegations in that behalf.

MAURICE T. SMITH,
U. S. Marshal,
. . . . Dist. of Colo.

By /s/ D. T. POTTER,
Deputy.

Marshal's Return

United States of America,
District of Colorado—ss.

I hereby certify that I caused the within notice to be published in *The Denver Democrat*, a weekly newspaper published in Denver, in said District, for three consecutive weeks prior to the 3rd day of March, A.D. 1947, and that a copy of this notice

has been posted on the premises wherein the goods seized in this cause are held by me, and also in the office of the Clerk of the United States District Court, at Denver, in said District, in accordance with a writ of monition and attachment in this cause issued out of the United States District Court at Denver, in said District, on the 8th day of January, A.D. 1947.

Affidavit of publisher is hereto attached and made a part hereof.

MAURICE T. SMITH,
U. S. Marshal,

By /s/ D. T. POTTER,
Deputy.

[Endorsed]: Filed March 17, 1947, U.S.D.C.,
District of Colorado.

[Endorsed]: Filed March 20, 1947, U.S.D.C.,
Northern District of California, Southern Division.

In the District Court of the United States for the
Northern District of California, Southern Division

In Admiralty No. 24872-H

THE UNITED STATES OF AMERICA,
Libelant,

vs.

33 BOTTLES, MORE OR LESS, OF AN AR-
TICLE LABELED IN PART "RI-CO TAB-
LETS HOMEOPATHIC COMBINATION
APP. 275 TABLETS"

ALBERTY FOOD PRODUCTS CO., a Copart-
nership, Consisting of ADA J. ALBERTY,
HARRY R. ALBERTY, HELEN M. AL-
BERTY HACKWORTH, KENNETH J.
HACKWORTH, FLORENCE M. ALBERTY
ST. CLAIR and MARGARET M. ALBERTY
QUINN,

Claimant.

CLAIM OF OWNER

To the Honorable Judges of the District Court of
the United States for the Northern District of
California:

Now appears Alberty Food Products Co., a co-
partnership, consisting of Ada J. Alberty, Harry
R. Alberty, Helen M. Alberty Hackworth, Kenneth
J. Hackworth, Florence M. Alberty St. Clair and
Margaret M. Alberty Quinn, intervening for the
interest of itself as the owner of said 33 bottles,

more or less, of an article labeled in part "RI-CO Tablets Homeopathic Combination App. 275 Tablets" before this Honorable Court and makes claim to said products as the same are attached by the Marshal under process of this Court and at the instance of the United States of America, Libelant, and the said Claimant avers that it was, at the time of the filing of the libel herein, and still is, bona fide sole owner of said products and that no other person is the owner thereof;

Wherefore, it prays to defend accordingly.

ALBERTY FOOD
PRODUCTS CO.,

By /s/ ADA J. ALBERTY,
Copartner.

/s/ GEORGE H. HAUERKEN,
HAUERKEN, AMES &
ST. CLAIR.

State of California,
County of Los Angeles—ss.

Ada J. Alberty, being duly sworn, deposes and says:

That she is a copartner in the firm of Alberty Food Products Co., a claimant herein, and as such is authorized to subscribe to oaths on behalf of said copartnership; that she has read the foregoing claim and knows the contents thereof and the same is true of her own knowledge, except as to the matters therein stated to be alleged upon information

and belief, and as to those matters she believes it to be true.

/s/ ADA J. ALBERTY.

Subscribed and sworn to before me this 24th day of March, 1947.

[Seal] /s/ AUGUST D. BARTOL,
Notary Public in and for the County of Los Angeles, State of California.

Receipt of copy admitted.

[Endorsed]: Filed April 7, 1947.

[Title of District Court and Cause.]

EXCEPTIONS TO LIBEL

To the Honorable Judges of the Southern Division of the United States District for the Northern District of California:

Alberty Food Products Company, a copartnership, consisting of Ada J. Alberty, Harry R. Alberty, Helen M. Alberty Hackworth, Kenneth J. Hackworth, Florence M. Alberty St. Clair and Margaret M. Alberty Quinn, excepts to the libel herein upon the following grounds:

I.

That the facts averred in the libel are insufficient to constitute a cause of action.

II.

That the facts averred in the libel are insufficient to constitute a cause of action in that it appears on

the face of the libel that the labeling of the article, the condemnation of which is sought by libelant, did bear adequate directions for use as required by Section 352(f)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A., and that said article can accordingly not be deemed to be misbranded within the meaning of said Act, as alleged in the libel.

III.

That the facts averred in the libel are insufficient and indistinct in that it cannot be ascertained therefrom in what respect the labeling of the said article failed to bear adequate directions for use as required by said Act.

IV.

That the facts averred in the libel are insufficient to constitute a cause of action in that it appears on the face of the libel that the alleged misbranding of said article is but a failure to include on the label of said article information not required by said Act to be included thereon, either as directions for the use of said article, or otherwise, and that the alleged misbranding is accordingly no misbranding at all within the meaning of said Act.

Wherefore, claimant prays that the libel be dismissed with costs.

/s/ GEORGE H. HAUERKEN,
HAUERKEN, AMES &
ST. SLAIR,
Attorneys for Claimant.

Receipt of copy attached.

[Endorsed]: Filed May 15, 1947.

[Title of District Court and Cause.]

ORDER

Claimant's exceptions having been briefed, argued and submitted for decision;

It Is Hereby Ordered that the exceptions be and the same are overruled.

Dated: September 30, 1947.

/s/ GEORGE B. HARRIS,
U. S. District Court.

[Endorsed]: Filed September 30, 1947.

[Title of District Court and Cause.]

ANSWER TO LIBEL

Alberty Food Products Co., a copartnership, consisting of Ada J. Alberty, Harry R. Alberty, Helen M. Alberty Hackworth, Kenneth J. Hackworth, Florence M. Alberty St. Clair and Margaret M. Alberty Quinn, respondents and claimants of 33 bottles, more or less, of an article labeled in part "RICO Tablets Homeopathic Combination App. 275 Tablets" for answer to the libel of the United States of America against said products, admit, deny and allege as follows:

I.

Deny the allegations contained in Article I.

II.

Admit the Allegations in Article II.

III.

Admit the allegations in Article III.

IV.

Deny the allegations in Article IV and V.

Wherefore, respondents and claimants pray that the libel herein be dismissed and that a decree be made herein directing the return of the products indicated in the caption hereof, and for costs of court and for such other relief as the case may require.

/s/ GEORGE H. HAUERKEN,
HAUERKEN, AMES &
ST. CLAIR,
Attorneys for Respondents
and Claimants.

State of California,
County of Los Angeles—ss.

Ada J. Alberty, being duly sworn, deposes and says:

That affiant is a copartner in the firm of Alberty Food Products Co., claimant herein, and as such is authorized to subscribe to oaths on behalf of said copartnership; that she has read the foregoing Answer and knows the contents thereof and that the same is true of her own knowledge, except as to the matters therein stated on information and belief and as to those matters she believes it to be true.

/s/ ADA J. ALBERTY.

Subscribed and sworn to before me this 18th day of November, 1947.

[Seal] /s/ RUTH C. POOL,
Notary Public in and for the County of Los Angeles, State of California.

Receipt of copy attached.

[Endorsed]: Filed December 1, 1947.

[Title of District Court and Cause.]

DEMAND OF CLAIMANTS AND
RESPONDENTS FOR TRIAL BY JURY

To the Honorable Judges of the Southern Division of the United States District Court, for the Northern District of California, and to the Clerk of said Court, and to the United States of America, and to Frank J. Hennessey, United States Attorney:

You are hereby notified that the Claimants and Respondents herein do hereby demand that all issues of fact joined in the above-entitled case shall be tried by a jury.

Dated: November 14, 1947.

/s/ GEORGE H. HAUERKEN,
HAUERKEN, AMES &
ST. CLAIR,
Attorneys for Claimants
and Respondents.

Receipt of copy attached. .

[Endorsed]: Filed December 1, 1947.

[Title of District Court and Cause.]

MOTION FOR SUMMARY JUDGMENT

The United States now moves the Court for a summary judgment of condemnation on the grounds:

(1) There are no facts in dispute.

(2) The only legal issue has been decided in favor of the United States by this Court in its order of September 30, 1947, overruling Claimant's exceptions to the libel. Under this ruling, a drug is misbranded if its labeling fails to state the purpose or condition for which it is intended.

Attached to our brief in support of this motion are a number of affidavits. The affidavit of McKay McKinnon, Chief of the San Francisco Station, U. S. Food and Drug Administration, appends the complete labeling and the advertising of Ri-co Tablets. This affidavit shows that the labeling does not state the purpose or condition for which the drug is intended.

The other affidavits, of physicians, indicate the therapeutic worthlessness of Ri-co Tablets and support the Government's contention that after entry of a decree of condemnation, this Court in its discretion should order the tablets destroyed rather

than afford the Claimant an opportunity to relabel them.

Respectfully submitted,

FRANK J. HENNESSY,
United States Attorney,

/s/ EDGAR R. BONSTALL,
Assistant U. S. Attorney.

Receipt of copy attached.

[Endorsed]: Filed October 15, 1948.

United States District Court for the Northern
District of California, Southern Division

ORDERED MOTION FOR SUMMARY
JUDGMENT SUBMITTED

At a Stated Term of the Southern Division of the United States District Court for the Northern District of California, held at the Court Room thereof, in the City and County of San Francisco, on Thursday, the 10th day of November, in the year of our Lord one thousand nine hundred and forty-nine.

Present: The Honorable Lloyd L. Black,
District Judge.

[Title of Cause.]

Case came on for hearing of motion for summary judgment, also for pre-trial conference. Edgar R. Bonsall, Esq., Asst. U. S. Atty., for libelant. Arthur A. Dickerman, Esq., Attorney for Food & Drug

Administration. George H. Hauerken, Esq., present as attorney for claimant, Alberty Foods Products Company, a copartnership.

Mr. Bonsall made a motion that Arthur A. Dickerman, Esq., be admitted to practice as an attorney of this Court for this case only, which motion was ordered granted.

After hearing Mr. Dickerman, Mr. Bonsall and Mr. Hauerken, Ordered that this case stand submitted to the Court for consideration and decision.

Further ordered that this case be continued to November 16, 1949, at 9:30 a.m. for decision.

MOTION FOR SUMMARY JUDGMENT
ORDERED GRANTED; CLAIMANT'S AP-
PLICATION FOR LEAVE TO SALVAGE
SEIZED TABLETS FOR RELABELING
ORDER DENIED

At a Stated Term of the Southern Division of the United States District Court for the Northern District of California, held at the Court Room thereof, in the City and County of San Francisco, on Wednesday, the 16th day of November, in the year of our Lord one thousand nine hundred and forty-nine.

Present: The Honorable Lloyd L. Black,
District Judge.

[Title of Cause.]

Case having been heretofore submitted, and due consideration thereon had, Ordered that the motion

for summary judgment be granted. Further ordered that claimant's application for leave to salvage seized tablets for relabeling be denied.

[Title of District Court and Cause.]

FINDINGS OF FACT
CONCLUSIONS OF LAW

Findings of Fact

(1) On or about November 25, 1946, Alberty Food Products caused to be transported from Hollywood, California, to Denver, Colorado, 33 bottles, more or less, of a drug labeled in part "Ri-co Tablets."

(2) Said shipment was held in the possession of Leeds Health House, Denver, Colorado.

(3) In January of 1947, the United States filed a Libel of Information in the U. S. District Court for the District of Colorado, alleging that said drug was misbranded and praying seizure and condemnation of said shipment. Pursuant to said Libel and process issued thereunder, the United States Marshal for the District of Colorado seized the Ri-co Tablets proceeded against.

(4) Alberty Food Products Co., a copartnership, intervened as claimant in this proceeding and effected a removal of the action to the U. S. District Court for the Northern District of California.

(5) Said Ri-co Tablets are a drug within the meaning of 21 U.S.C. 321(g)(2) since they were intended for use in the treatment, mitigation, and cure of arthritis and rheumatism.

(6) The label affixed to each bottle of said Ri-co Tablets reads as follows:

[Front Panel]

Ri-co
Tablets

Homeopathic
Combination

App. 275 Tablets

Each Tablet Contains:

Lithium Benzoicum

Ammonium Phos.

Lycopodium

Mfg. for and Packed by

Alberty Food Prod.

Hollywood, Calif.

[Side Panel]

Directions:

Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed.

[Side Panel]

Directions:

Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed.

(7) The labeling of said Ri-co Tablets does not mention any disease condition.

(8) The labeling of said Ri-co Tablets fails to bear adequate directions for use in that it fails to declare the diseases or conditions of the body for which claimant offered the drug to the public, and for which claimant intended the drug to be used.

(9) The United States has filed a motion for Summary Judgment, supported by affidavits.

(10) Claimant does not seriously contend that the Ri-co Tablets are not misbranded as they are presently labeled, and proposes to consent to a decree of condemnation provided claimant is permitted to relabel said drug so as to conform with language in a Federal Trade Commission Order.

(11) There is no genuine issue as to any material fact that remains unresolved with respect to the question whether the Ri-co Tablets under seizure, as presently labeled, are misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

(12) The claimant, Alberty Food Products Co., and especially one of its partners, Ada J. Alberty, have been persistent violators of the Federal Food, Drug, and Cosmetic Act for many years.

(13) The Federal Trade Commission Order in question was based upon a Stipulation of Facts. The pertinent portion of the Order, as cited by the claimant, reads as follows:

“It is ordered . . . to forthwith cease and desist from 1. Disseminating or causing to be disseminated any advertisement by means of the United States mails, or by any means in commerce, as ‘commerce’ is defined in the Federal Trade Commission Act, which advertisement represents, directly or by implication:

(a) That the preparation ‘*Ri-co Tablets*’ constitutes an adequate or competent treatment for arthritis, rheumatism, gout or ‘*rheumatic gout*’; or that said preparation will eliminate uric acid from the system; provided, however, that nothing herein shall be construed as prohibiting the representation that according to the principles of the homeopathic school of medicine the preparation is of value in ameliorating the symptoms of muscular or ligamentous pain and stiffness due to arthritis or rheumatism, except when such symptoms are accompanied by a febrile condition.”

(14) The Federal Trade Commission Order does not hold that *Ri-co Tablets* are of value in ameliorating the symptoms of muscular or ligamentous pain and stiffness due to arthritis and rheumatism, etc. Said Order merely indicates that the Federal Trade Commission was not preventing *Alberty Food Products Co., et al.* from representing that *Ri-co Tablets* are of value for such purposes according to the principles of the homeopathic school of medicine.

(15) It is not necessary for this Court to determine whether Ri-co Tablets are worthless. The Government has submitted affidavits from prominent medical authorities, including homeopathic doctors, all to the effect that Ri-co Tablets are worthless. Claimant has made no showing that Ri-co Tablets have any efficacy or value. There is no showing of any loss to humanity or posterity if the Ri-co Tablets under seizure are destroyed.

Conclusions of Law

(1) The Ri-co Tablets here involved were shipped in interstate commerce from Hollywood, California, to Denver, Colorado.

(2) Said Ri-co Tablets were seized by the United States Marshal for the District of Colorado within the jurisdiction of the U. S. District Court for that District, pursuant to 21 U.S.C. 334(a). The jurisdiction of the U. S. District Court for the Northern District of California derives from an Order of the U. S. District Court for the District of Colorado removing the instant cause to this District on application of the claimant, pursuant to 21 U.S.C. 334(a).

(3) Said Ri-co Tablets are a drug under the Federal Food, Drug and Cosmetic Act within the meaning of 21 U.S.C. 321(g)(2).

(4) A drug is misbranded under 21 U.S.C. 352(f)(1) unless its labeling bears "adequate directions for use."

(5) The labeling of a drug does not bear adequate directions for use unless, among other things, it states the diseases or conditions of the body for which the drug is offered to the public.

(6) In seizure actions pursuant to 21 U.S.C. 334(a) and (b), the Admiralty Rules are applicable until seizure of the allegedly offending article is accomplished. Thereafter, the Civil Rules apply.

(7) Under amended Civil Rule 56(c), a summary judgment should be rendered forthwith on motion if it is shown from the pleadings and affidavits on file that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.

(8) The proviso in 21 U.S.C. 334(b) "that on demand of either party any issue of fact joined in any such case shall be tried by jury" does not entitle the claimant in a seizure action to a jury trial where there is no genuine issue as to any material fact, and where consequently there is no triable issue of fact.

(9) The aforesaid Ri-co Tablets under seizure here were misbranded within the meaning of 21 U.S.C. 352 (f)(1) when introduced into and while in interstate commerce in that the labeling of said drug fails to state the diseases or conditions of the body for which the drug was offered to the public by the claimant.

(10) Said Ri-co Tablets are subject to condemnation pursuant to 21 U.S.C. 334(a), and libellant

is entitled to a summary judgment ordering such condemnation.

(11) Whether a claimant should be afforded the privilege of relabeling or otherwise salvaging a condemned article is a matter which is left to the discretion of the District Court by 21 U.S.C. 334(d).

(12) A Cease and Desist Order issued by the Federal Trade Commission regarding representations made for a drug is not *res judicata* with respect to similar representations proposed for the relabeling of a drug which has been condemned as misbranded in violation of the Federal Food, Drug, and Cosmetic Act.

(13) The power of the District Court to condemn misbranded articles under the Federal Food, Drug, and Cosmetic Act is not impaired, diminished, or in any wise affected by the possibility that such misbranding may also be the subject of a cease and desist order of the Federal Trade Commission or even by the fact, if it be a fact, that such an order has actually issued.

(14) The District Court has discretion to permit relabeling of a condemned article, but, for the Court to allow a claimant who has violated the law to relabel, the claimant should make an affirmative showing that appeals to the judgment and conscience of the Court.

(15) Claimant is not entitled to relabel the aforesaid Ri-co Tablets, which should instead be destroyed.

(16) Libelant is entitled to its costs herein, pursuant to 21 U.S.C. 334(e).

Dated: November 29, 1949.

/s/ LLOYD S. BLACK,
U. S. District Judge.

Requested by:

EDGAR R. BONSALE,
Asst. U. S. Atty.,
Atty for Libelant.

Receipt of copy attached.

Lodged November 23, 1949.

[Endorsed]: Filed November 29, 1949.

In the District Court of the United States for the
Northern District of California, Southern Division

In Admiralty No. 24872-H

THE UNITED STATES OF AMERICA,

Libelant,

vs.

33 BOTTLES, MORE OR LESS, OF AN ARTICLE
LAELEL IN PART "RI-CO TABLETS
HOMEOPATHIC COMBINATION
APP. 275 TABLETS"

and

ALBERTY FOOD PRODUCTS CO., Etc.,

Claimant.

DECREE OF CONDEMNATION
AND DESTRUCTION

Pursuant to the Findings of Fact and Conclusions of Law entered this day by the Court in this proceeding in accordance with the oral opinion of this Court handed down on November 16, 1949, it is

Ordered, Adjudged, and Decreed that the aforesaid article of drug under seizure, namely, Ri-co Tablets, is misbranded in violation of 21 U.S.C. 352 (f)(1), and is hereby condemned and ordered destroyed by the United States Marshal pursuant to 21 U.S.C. 334(a) and (d), and that said Marshal shall make his return into Court in this matter; and it is further

Ordered, Adjudged, and Decreed, pursuant to 21

U.S.C. 334(e), that the United States of America shall recover from the claimant, Alberty Food Products Co., court costs, and fees, and storage and other proper expenses.

Dated: November 23, 1949.

/s/ LLOYD S. BLACK,
U. S. District Judge.

Receipt of copy attached.

Lodged November 23, 1949.

[Endorsed]: Filed and entered Nov. 29, 1949.

[Title of District Court and Cause.]

PETITION FOR APPEAL

Alberty Food Products Co., a copartnership consisting of Ada J. Alberty, Harry R. Alberty, Helen M. Alberty Hackworth, Kenneth J. Hackworth, Florence M. Alberty St. Clair and Margaret M. Alberty Quinn, claimant herein, being aggrieved by the decree of condemnation and destruction entered herein on the 29th day of November, 1949, by the above-entitled Court, claims an appeal from said decree and prays that said appeal may be allowed.

Dated: This 15th day of December, 1949.

/s/ GEORGE H. HAUERKEN,
HAUERKEN, AMES &
ST. CLAIR,
Attorneys for Claimant.

[Endorsed]: Filed December 16, 1949.

[Title of District Court and Cause.]

ORDER ALLOWING APPEAL

Pursuant to the petition for appeal of Alberty Food Products Co., a copartnership consisting of Ada J. Alberty, Harry R. Alberty, Helen M. Alberty Hackworth, Kenneth J. Hackworth, Florence M. Alberty St. Clair and Margaret M. Alberty Quinn, claimant herein, dated December 15, 1949, and presented this date to the Court:

It Is Hereby Ordered that the appeal of said claimant from the decree of condemnation and destruction entered herein on the 29th day of November, 1949, be allowed as prayed for and that said claimant file a cost bond on appeal of a corporate surety in the amount of Two Hundred Fifty (\$250.00) Dollars and that, upon the filing of said bond, all proceedings under said decree be stayed.

Dated: This 16th day of December, 1949.

/s/ LOUIS GOODMAN,
U. S. District Judge.

[Endorsed]: Filed December 16, 1949.

[Title of District Court and Cause.]

NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Notice is hereby given that Alberty Food Products Co., a copartnership consisting of Ada J. Al-

berty, Harry R. Alberty, Helen M. Alberty Hackworth, Kenneth J. Hackworth, Florence M. Alberty St. Clair and Margaret M. Alberty Quinn, claimants herein, hereby appeal to the United States Court of Appeals for the Ninth Circuit from the final decree of condemnation and destruction entered in the above-entitled proceeding on the 29th day of November, 1949, and from each and every part thereof.

/s/ GEORGE H. HAUERKEN,
HAUERKEN, AMES &
ST. CLAIR,
Attorneys for Claimant.

Receipt of service attached.

[Endorsed]: Filed December 16, 1949.

WRIT OF DESTRUCTION

No. 24872-H

[Title of District Court.]

The President of the United States of America
To the Marshal of the District of Colorado, Greeting:

Whereas, an information was filed in the United States District Court for the District of Colorado on the 7th day of March, A.D. 1947, by Frank J. Morrissey, United States Attorney, on behalf of the United States of America, against 33 Bottles, more or less, of an Article labeled in Part: "Ri-co

Tablets Homeopathic Combination App. 275 Tablets," and praying that the same may be condemned as forfeited to the use of the said United States. And whereas the said goods, wares, and merchandise have been attached by the process issued out of the said District Court of Colorado in pursuance of the said information and are now in custody by virtue thereof; and such proceedings have been thereupon had that by the final sentence and decree of the District Court of California in this cause made and pronounced, on the 29th day of November, A.D. 1949, the said goods, wares, and merchandise were ordered to be destroyed by you, the said Marshal for the District of Colorado, according to law. And that you have this Writ at a United States District Court, to be held for the Northern District of California at the City of San Francisco, on the 20th day of December, A.D. 1949.

Therefore, you, the said Marshal for the District of Colorado, are hereby commanded to cause the said goods, wares, and merchandise so ordered to be destroyed, to be destroyed in manner and form, upon the notice, and at the time and place by law and order of Court required. And that you have also then and there this Writ.

Witness, the Honorable Lloyd L. Black, United States Judge at San Francisco, this 29th day of November, A.D. 1949.

C. W. CALBREATH,

Clerk.

[Seal] By /s/ E. H. NORMAN,

Deputy Clerk.

In obedience to the above precept, I have destroyed the said goods, wares, and merchandise as I am above commanded.

Dated this 14th day of December, 1949.

MAURICE T. SMITH,
U. S. Marshal,

By /s/ OSCAR A. CRIST,
Deputy Marshal.

[Endorsed]: Filed December 19, 1949.

[Title of District Court and Cause.]

ORDER EXTENDING TIME TO DOCKET

Good cause appearing therefor, it is hereby ordered that the appellant herein may have to and including February 24, 1950, to file the record on appeal in the United States Court of Appeals for the Ninth Circuit.

Dated: January 24, 1950.

/s/ LOUIS E. GOODMAN,
U. S. District Judge.

Approved 1/24/50.

/s/ EDGAR R. BONSALE,
Asst. U. S. Atty.

[Endorsed]: Filed January 24, 1950.

CITATION ON APPEAL

United States of America—ss.

The President of the United States of America
To the United States of America, Greeting:

You Are Hereby Cited and Admonished to be and appear at a United States Court of Appeals for the Ninth Circuit, to be holden at the City of San Francisco, in the State of California, within thirty days from the date hereof, pursuant to an order allowing an appeal, of record in the Clerk's Office of the United States District Court for the Northern District of California, Southern Division, wherein Alberty Food Products Co., a co-partnership consisting of Ada J. Alberty, Harry R. Alberty, Helen M. Alberty Hackworth, Kenneth J. Hackworth, Florence M. Alberty St. Clair and Margaret M. Alberty Quinn, No. 24872, claimant and appellant, and you are appellees, to show cause, if any there be, why the decree or judgment rendered against the said appellant, as in the said order allowing appeal mentioned, should not be corrected, and why speedy justice should not be done to the parties in that behalf.

Witness, the Honorable Louis E. Goodman, United States District Judge for the Northern District of California, Southern Division, this 9th day of February, A.D. 1950.

/s/ LOUIS E. GOODMAN,
U. S. District Judge.

Service of copy acknowledged.

[Endorsed]: Filed February 9, 1950.

[Title of District Court and Cause.]

ASSIGNMENT OF ERRORS AND STATEMENT OF POINTS RELIED UPON ON APPEAL

Appellant hereby assigns error in the proceedings, orders and decisions of the District Court in the above-entitled cause and hereby states the points upon which it intends to rely on appeal as follows:

(1) The court erred in holding that Ri-Co Tablets were misbranded and in ordering their condemnation and destruction.

(2) The court erred in finding and holding that the labeling of Ri-Co Tablets fails to bear adequate directions for use in that it does not declare the diseases or conditions of the body for which Ri-Co Tablets are offered to the public by appellant and for which appellant intends them to be used.

(3) The court erred in finding that appellant "does not seriously contend that the Ri-Co Tablets are not misbranded as they are presently labeled."

(4) The court erred in deciding this case under rules applicable to civil cases instead of deciding it under rules applicable to admiralty cases, and particularly in holding that the summary judgment procedure provided by rule 56 of the Federal Rules of Civil Procedure is applicable to a proceeding for the condemnation of a drug and in applying that procedure to this condemnation proceeding.

(5) The court erred in finding and holding that

no genuine issue as to any material fact remains unresolved with respect to the question of whether Ri-Co Tablets were misbranded; the court accordingly erred in granting the motion for summary judgment.

/s/ GEORGE H. HAUERKEN,

HAUERKEN, AMES &

ST. CLAIR,

Attorneys for Claimant,

Alberty Food Products Co.

Receipt of copy attached.

[Endorsed]: Filed February 9, 1950.

[Title of District Court and Cause.]

PRAECIPE FOR APOSTLES ON APPEAL
AND DESIGNATION OF PORTIONS OF
RECORD, PROCEEDINGS, AND EVIDENCE
TO BE CONTAINED IN RECORD
ON APPEAL

To the Clerk of the Above-Entitled Court:

Claimant and appellant herein, having appealed to the United States Court of Appeals for the Ninth Circuit from the decree of condemnation and destruction made and entered herein by the above-entitled Court on November 29, 1949, hereby designates the following portions of the record, proceedings and evidence as the portions of the record, proceedings and evidence to be contained in the

record on appeal and hereby request you to prepare and certify apostles on appeal, to be filed in said Court of Appeals in due course, and to include the following in said apostles:

All of the original papers on file herein, including this praecipe and designation, and particularly all of the papers required to be included by Rule 75 of the Federal Rules of Civil Procedure, and by Rule 37 of the Rules of the United States Court of Appeals for the Ninth Circuit.

/s/ GEORGE H. HAUERKEN,

HAUERKEN, AMES &
ST. CLAIR,

Attorneys for Claimant,
Alberty Food Products Co.

Receipt of copy attached.

[Endorsed]: Filed February 9, 1950.

In the Southern Division of the United States District Court for the Northern District of California

No. 24,872-H in Admiralty

THE UNITED STATES OF AMERICA,

Libelant,

vs.

33 BOTTLES, MORE OR LESS, OF AN ARTICLE LABELED IN PART "RI-CO TABLETS HOMEOPATHIC COMBINATION APP. 275 TABLETS," ALBERTY FOOD PRODUCTS CO., ETC.,

Claimant.

Before: Hon. Lloyd L. Black,
Judge.

REPORTER'S TRANSCRIPT

Wednesday, November 16, 1949

Appearances:

For Libelant:

ARTHUR A. DICKERMAN, ESQ.,

EDGAR R. BONSALE, ESQ.,

For Claimant:

GEORGE H. HAUERKEN, ESQ.

DECISION ON MOTION FOR
SUMMARY JUDGMENT

The Clerk: United States v. 33 Bottles of Ri-Co Tablets. Motion for Summary Judgment, for decision.

Mr. Hauerken: Ready.

Mr. Dickerman: Your Honor, may I request I be heard briefly on a new development that came to my attention this morning. It involves another case, or another libel with the Food and Drug Law wherein the District Court of the Northern District of Illinois granted motion for summary judgment. I have a mimeographed copy of this opinion which I received this morning. I gave a copy to counsel.

The Court: You may hand it to me.

Mr. Dickerman: I wish to call the attention of the Court, the question apparently was not raised as to whether the admiralty or civil rules applied.

The Court: In the matter of the United States of America v. 33 Bottles, More or Less, of an Article Labeled in Part "Ri-Co Tablets Homeopathic Combination App. 275 Tablets," Alberty Food Products Co., etc., Claimant, the Government is asking for summary judgment. The claimant suggested in the first instance that summary judgment is not applicable on the ground that under the statutes the proceeding is to be considered as one in admiralty, and that therefore the civil rules of Federal Procedure providing for summary judgment do not authorize action by the Court as requested by the Government.

I say that the claimant has suggested that summary judgment is not applicable. Actually, counsel for claimant has further suggested to the Court that condemnation is appropriate and should be ordered, but that the Court should further provide that the claimant should be permitted to relabel the bottles in accordance with the practice counsel says the claimant is now following pursuant to a decision by the Federal Trade Commission. In effect, then, I take it the question of whether or not this is a proceeding in admiralty is, in so far as counsel is able to make it, somewhat academic. It might almost be said that it is the law of this particular case that condemnation on the record should enter, and that the issue is whether or not relabeling should be permitted.

I have looked at the authorities: the decision of the Supreme Court in 226 U.S., beginning at page 172; 33 Supreme Court, beginning at page 50; and 57 Law Edition, page 175, has been cited to the Court by the Government as establishing that this proceeding is civil and is not one in admiralty. That Supreme Court decision in substance held that the law then before the Supreme Court likened the proceedings to one admiralty in connection with the seizure of the property by process in rem, and that decision of the United States Supreme Court in effect was that after the seizure the matter became a proceeding in law and was governed by the statutes and rules apart from admiralty.

Counsel for the plaintiff has pointed out that that decision was before the enactment of the pres-

ent statute. After reading the Supreme Court decision, it seems to me that the principal therein enunciated, properly applied to the present statute, strongly indicates that it is to be deemed a civil rather than an admiralty matter after the seizure. It would therefore appear that summary judgment would be applicable.

My view of the force and effect of that Supreme Court decision, which I think was about 1912, is in harmony with the view of the Circuit Court of Appeals for the Sixth Circuit, after the enactment of the present statute, which decision was rendered June 22, 1943, and is found in 136 Fed. Rep., 2nd Series, beginning at page 523. The Court of Appeals of the Sixth Circuit, in substance, held that the proceeding was not intended to be likened to one in admiralty beyond the seizure of the property by process in rem under the statutes.

Under the decisions cited to me, I am satisfied that the Federal Rules of Civil Procedure are effective and that a summary judgment, upon proper showing, can be entered.

There has just been handed to me District Court decision from the Northern District of Illinois, *United States v. 17 Cases, More or Less, of Nue-Ovo, Research Laboratories, Inc.* In this decision, dated October 11, 1949, the judge assumed that entry of a summary judgment was within his authority. It does not appear, however, that anyone objected to his exercising the authority providing the showing was sufficient. But independently

of this most recent decision, I am satisfied that the proceeding is, at this stage, not one in admiralty. The main contention of the claimant is that by virtue of the Federal Trade decision, the holding that its right to relabel these articles is established be on the doctrine of *res adjudicata*. Such is a most interesting contention. Counsel for claimant depends primarily upon the decision of the United States v. Willard Tablet Company, 141 Fed. (2d), beginning at page 141, being a decision by the Circuit Court of Appeals of the Seventh Circuit under date of March 7, 1944. That court undoubtedly does hold that a decision by the Federal Trade Commission is binding upon the court in an independent proceeding; and the court in that decision depended upon an earlier decision by the Circuit Court of Appeals for the Eighth Circuit in *Lee v. Federal Trade Commission*, 113 Fed. (2d) 583. However, the Circuit Court of Appeals for the Ninth Circuit, under date of February 24, 1942, in *U. S. v. Research Laboratories, Inc.*, reversing a holding by myself at Tacoma, said the following:

“It is immaterial, if true, that the makers and advertisers of Nue-Ovo could have been proceeded against by the Federal Trade Commission under the Federal Trade Commission Act and could have been ordered to cease and desist from publishing and distributing the circular entitled ‘What Is Arthritis?’ The power of the District Court to condemn misbranded articles is not impaired, diminished, or in any wise affected by the possibility that such misbranding may also be the subject of

a cease and desist order or either by the fact, if it be a fact, that such an order has actually issued.”

I am bound and controlled by the decision of this circuit, regardless of whether I agree or disagree with its correctness. I am only to be persuaded by the decisions of the Seventh Circuit or the Eighth Circuit if they appeal to my reason and are not at variance with the decisions of the Court of Appeals for the Ninth Circuit.

December 8, 1943, 139 Fed. Rep. (2d), page 197, in the *Sekov Corporation v. United States*, the Circuit Court of Appeals for the Fifth Circuit cited with approval the decision of 122 Fed. (2d) 42, U. S. v. *Research Laboratories*, of this Ninth Circuit, which I have just mentioned.

Mr. Hauerken: Your Honor, may I say a word?

The Court: It stated this:

“Appellant *Sekov Corporation* contends that the fact that it had been previously proceeded against by the Federal Trade Commission barred inquiry by the District Court into the questions presented by the Government’s libel. There is no merit in this contention. The issues in that proceeding were not identical with those here presented. Moreover, the power and duty of the District Court to condemn the misbranded articles was not impaired or diminished by the former proceeding. *United States v. Research Laboratories*, 9 Cir., 126 Fed. (2d) 42, 45.”

While the decision of the Eighth Circuit in 113 Fed. (2d) 583, which I previously mentioned, ap-

pealed to the Court of Appeals for the Seventh Circuit in the Willard Tablet Company case, such decision in 113 Fed. (2d) neither appealed to the Circuit Court of Appeals for the Fifth Circuit nor to the Circuit Court of Appeals for the Ninth Circuit.

Unquestionably I must hold that what the Federal Trade Commission did in an independent and different proceeding is not *res adjudicata* here. Actually, such would appear not to be *res adjudicata* for further reasons. In the first place, what the Trade Commission did apparently was done pursuant to stipulation. Other courts, in independent proceedings where the showing is different, are very reluctant to consider themselves barred by a commission's holding on a stipulation. Further than that, I do not find that the Commission held anything. I am advised that the cease and desist order of the Federal Trade Commission required this claimant to cease and desist from disseminating advertisements in the United States mails or by any means in commerce which represent "that the preparation 'Ri-Co Tablets' constitutes an adequate or competent treatment for arthritis, rheumatism, gout or rheumatic gout; or that said preparation will eliminate uric acid from the system; provided, however, that nothing herein shall be construed as prohibiting the representation that according to the principles of the homeopathic school of medicine the preparation is of value in ameliorating the symptoms of muscular or ligamentous pain and stiffness due to arthritis or rheumatism except when

such symptoms are accompanied by a gebrile condition.”

It is apparent that the Federal Trade Commission did not hold that Ri-Co Tablets were of value to ameliorate the symptoms of muscular or ligamentous pain and stiffness due to arthritis or rheumatism. The most that the Federal Trade Commission said was that it was not preventing the claimant from contending that such was of benefit. That is a far cry from any adjudication that should be considered as *res adjudicata*.

But even if the Federal Trade Commission had done what counsel feels it did do, the Circuit Court of Appeals for the Ninth Circuit certainly told me that any holding of any Federal Trade Commission was of no avail in another and independent proceeding before the District Court. There is no showing in behalf of the claimant before me that the tablets have any efficiency or any value. All of the showing, so far as presented, is to the effect that they are worthless.

The application for summary judgment based upon the pleadings, however, is upon the ground that the labels did not give adequate directions as required by the statute. The label did state that the tablets were to be taken at certain intervals, without even a hint that the tablets were helpful for anything. The Government's contention is that the directions, to be adequate, must not only tell how often the alleged remedy is to be taken, but for what it is to be used. The decisions of the Circuit Court

of Appeals in this Circuit, both of the District Courts and of the Court of Appeals, are to the effect that as to remedies' directions, to be adequate they must not only say how often but for what.

It seems to me that such holdings which are binding upon me are in accord with reason and in harmony with the purpose of the Pure Food and Drug Act.

The condemnation asked will be ordered upon the ground that the directions printed did not comply with the statute; upon the ground that they were inadequate.

I am not holding that *Ri-Co Tablets* are worthless. That issue actually was not presented to me. The Court has the authority, in its discretion, to permit the claimant to relabel these tablets; but certainly for the Court to allow claimant which has violated the law to relabel tablets, the claimant should make an affirmative showing that appeals to the judgment or conscience or both of the Court. No showing whatsoever has been made. It is conceded that the claimant has been held repeatedly to have violated the law, either as to these tablets or other preparations. The claimant has not attempted to persuade me that the tablets are good and that there would be any loss to humanity or posterity if I allow condemnation to be effected. Claimant has relied solely upon the *Willard Tablet* case, which is a holding of the Northern Circuit and not binding on me, and which is contrary to a holding of this Circuit which does control.

I know no good reason that I should require the Government to turn over these tablets for relabeling. Judgment and order will be presented in conformity with my announcement.

Counsel, there was something you wished to say?

Mr. Hauerken: I presume it is too late inasmuch as your Honor has announced judgment. I do feel your Honor has erroneously construed the Research Laboratories Company case. I do not know whether your Honor wants me to be heard on this or not, but I would like to show my views on it.

The Court: Well, counsel, I told you I am quite familiar with that case. I am speaking now informally. It is not a part of my decision. I thought at the time I rendered decision in Tacoma that I was right. It might not be very hard for you to convince me that the Circuit Court was mistaken, but the Circuit Court reversed me and I am bound by what it said and certainly it said what I have quoted from it, because I read it verbatim. I have no quarrel with that portion of the Circuit Court's holding. I think, as I pointed out before to you, I have held the libel was so crudely and inexpertly drawn that it had no right to be considered by the Court and I dismissed it. The Circuit Court of Appeals in reversing me admitted the following:

“The libel is crudely and inexpertly drawn. It does not state directly and positively, as a competently drawn libel would have stated, that the 143 packages of Nue-Ovo were misbranded when introduced into or while in interstate commerce.”

But the Circuit Court of Appeals held that the crudeness and lack of expertness in the drawing of the libel, while not to be commended, was not as fatal as I thought it was. But I am satisfied now, upon upon the problem you present I have disagreed directly with you and disagreed directly with the doctrine of the Willard case on which you relied.

Mr. Hauerken: The point I make in that, that violation, if any, was a violation of the Federal Trade Commission Act and therefore there could be no prosecution under the Food and Drug Act, as I recall that case. The question was whether or not the pamphlets had accompanied the article in interstate commerce. Wasn't that the case where it was held common origin, common destination, and approximately a shipment at the same time constituted a libel? I think that is the case I have in mind.

The Court: Well, whatever was there at issue, the Circuit Court of Appeals announced the doctrine for this Circuit that answered your argument far better than any counsel could hope to answer it, and the Circuit Court of Appeals for the Fifth Circuit seemed to think that that doctrine was appropriate because, as I say, it disregarded the decision in 113 Fed. (2d) the court in the Willard case relied on.

Mr. Hauerken: My concept of that case is that a person could violate both acts, and I think that is what those cases hold, that by the one action you would be in violation of both acts.

The Court: I have no question of that, counsel, but both courts say in an independent proceeding

on different showings the court is not bound by what the Federal Trade Commission may do, and that is particularly true when what the Federal Trade Commission did, in so far as it did anything, was on stipulation; and most particularly true when the Federal Trade Commission didn't do anything, but just merely negatively said that its order was not to be construed as stopping you from doing something.

Mr. Hauerken: I merely wanted to present that point, your Honor. I have no desire to draw the matter out.

The Court: The Court will say this: It has been very interested in the presentation by counsel on both sides. Counsel on each side have been very helpful to the Court and have ably presented their various matters. I am sure I understood the presentation of counsel for claimant. Under the law as I see it, and the facts as presented, I am holding against him. He may be right, but I do not think so. I thank counsel on both sides for your assistance to the Court.

That is all.

Certificate of Reporter

I, K. J. Peck Official Reporter, certify that the foregoing page is a true and correct transcript of the matter therein contained as reported by me and thereafter reduced to typewriting to the best of my ability.

/s/ K. J. PECK.

[Endorsed]: Filed January 3, 1950.

[The following exhibits were attached to Brief in Support of Motion for Summary Judgment, filed Oct. 15, 1948.]

EXHIBIT NO. 2

In the District Court of the United States for the Northern District of California, Northern Division

In Admiralty No. 24872-H

THE UNITED STATES OF AMERICA,
Libellant,

vs.

33 BOTTLES, MORE OR LESS, OF AN ARTICLE LABELED IN PART "RI-CO TABLETS HOMEOPATHIC COMBINATION APP. 275 TABLETS"

ALBERTY FOOD PRODUCTS CO., a Copartnership, Consisting of ADA J. ALBERTY, HARRY R. ALBERTY, HELEN M. ALBERTY HACKWORTH, KENNETH J. HACKWORTH, FLORENCE N. ALBERTY ST. CLAIR, and MARGARET M. ALBERTY QUINN,

Claimant.

Affidavit of McKay McKinnon, Jr.

United States of America,
Northern District of California—ss.

State of California
County of San Francisco

Before me, Andrew J. Brown an employee of the

Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Mr. McKay McKinnon, Jr. in the County and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am Chief of the San Francisco Station of the Food and Drug Administration, Federal Security Agency and am in charge of the enforcement activities of the Station.

(2) The official records of the San Francisco Station contain an extensive file on the case of U. S. vs. 33 Bottles “*** Ri-co Tablets Homeopathic Combination App. 275 Tablets,” Admiralty No. 24872-H, now pending in the Northern District of California. There are stored under official seal at the San Francisco Station, official samples that were taken from the article under seizure.

(3) From the official records and official samples filed and stored at the San Francisco Station I have had copies made of the following items which are appended and identified as indicated:

Exhibit A—Photostats of complete labeling of a specimen of the Ri-co Tablets under seizure in this case.

Exhibit B—Advertisement for Ri-co Tablets which appeared in the Rocky Mountain News, Denver, Colorado, on October 1, 1946 on page 19.

Exhibit C—Advertisement for Ri-co Tablets which appeared in the San Francisco Chronicle on June 7, 1948.

(4) I have compared the photostats referred to with the originals in my possession and I certify that they are exact copies.

/s/ McKAY McKINNON, JR.

Signature.

Subscribed and sworn to before me at San Francisco, California, this 28th day of September, 1948.

/s/ ANDREW J. BROWN,

Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

11 Liberty H

Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed.

DIRECTIONS:

RI-CO
Tablets

HOMEOPATHIC
COMBINATION

App. 275 Tablets

Each Tablet Contains:

- Lithium Benzoate
- Ammonium Phosphate
- Lycosodium

Mfg. For and Pack. by
LIBERTY FOOD FOOD,
Hollywood, Ca

RI-
Tab

HOME
COMBINATION

App. 275

Each Tablet Contains:

- Lithium
- Ammonium
- Lycosodium

Mfg. For and Pack. by
LIBERTY FOOD FOOD,
Hollywood, Ca

DIRECTIONS:

Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed.

Mrs. Ima Clark Howard died at her home in Denver, Colo., at 11:30 a. m., tomorrow, in the presence of her husband, Dr. A. B. Howard. Her husband, Dr. A. B. Howard, died yesterday at his home in Aurora, She was 62. Born in Paducah, Ky., on Dec. 14, 1876, she was the daughter of W. H. and M. M. Howard. She was married to Mr. Howard in 1917.

In 1923, they moved to Aurora three years ago. She was an active member of the Garden Club while in Denver. She was a member of the Y. W. C. A. and the Y. W. C. A. auxiliary of the Garden Club. She was a member of the June Jefferson Club, she was on the reception committee when Mrs. Truman visited Denver.

Mrs. Howard also was a member of the Y. W. C. A. auxiliary of the Garden Club and the Y. W. C. A. auxiliary of the Garden Club. She was a member of the Y. W. C. A. auxiliary of the Garden Club and the Y. W. C. A. auxiliary of the Garden Club.

Funeral services for Mrs. Clark Howard will be held at 2 p. m. tomorrow at the home of her daughter, Mrs. E. M. Howard, 1215 S. W. 10th St., Denver.

Burial will be in the Garden of Eatin' cemetery, Denver.

Survivors include her husband, Dr. A. B. Howard, and two daughters, Mrs. E. M. Howard and Mrs. M. M. Howard.

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HOW COME THEY SAW THE ELVA CINDERS HERE TO TRY TO MAKE YOU BLUPPER ON FOR A DAY? MET

GET FRANKS TO TELL YOU QUOT OF YOU? HARK! ELVA RIZZON! ISN'T SHE LOVE! ALL SLOBBERING LOVE! TO LEAVE SLOWLY AND YOU DON'T KNOW HOW HEAVY IS RIGHT? "

ELVA CINDERS

Lost: One Princess

EVERYTHING AT THE RIZZON DOG!

WHAT IS THE RIZZON? THE HYENA!

BY CHARLES PLUMB AND FRED FOX

BY AL CAPP

WHAT IS THE RIZZON? THE HYENA!

BY CHARLES PLUMB AND FRED FOX

21 Nazi Leaders Guilty of War; Death Thought Sure for at Least 18

(Continued From Page 3)

connected with atrocities on the Eastern front—Russia, Poland and Czechoslovakia—would escape the death penalty.

They included: Adolf Hitler, Reich Chancellor; Hermann Goering, Reich Minister of War; Hans Frickhoff and Franz Pappein—might escape with prison sentences; but as they heard their names linked to some of the world's greatest crimes, their interest gave way to evident fatality and bewilderment.

For the most part they were not surprised. They had all been indicted, following the Nuremberg trial, by the International Military Tribunal set up by the United States, Great Britain, France and the Soviet Union.

In addition to the 21 defendants, 18 other members of the Nazi organization were killed by a Russian shell in Berlin, the court pronounced next.

The 18 were: 11 members of the three guilty organizations, 10 were imposed death sentences, and 10 were sentenced to life imprisonment.

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Chief Hanebuth Ordered Into Court

(Continued From Page 3)

when asked to explain his duties as chief of police. The transcript of the trial is being translated into English.

Chief Hanebuth, what your duties are as chief of police, that would include the following:

1. To maintain the peace and order in the city.

2. To protect the lives and property of the citizens.

3. To enforce the laws of the city.

4. To maintain the public safety.

5. To protect the interests of the city.

Seven Firemen Get Promotions

Six firemen were raised to the rank of lieutenant by the city council last night.

The promotions were: Joseph J. Kirschling, manager of the fire department; William J. Kirschling, assistant manager; Edward J. Kirschling, assistant manager; William J. Kirschling, assistant manager; Edward J. Kirschling, assistant manager; William J. Kirschling, assistant manager.



ARTHITIS RHEUMATISM

BICO TABLETS
Another Arthritis Product

Do you suffer from ARTHITIS or RHEUMATISM? Do you have stiff joints, swollen joints, or pain in the joints? Do you have difficulty in walking, or in climbing stairs, or in getting up and down? Do you have aching joints, or aching muscles, or aching bones? Do you have aching joints, or aching muscles, or aching bones? Do you have aching joints, or aching muscles, or aching bones?



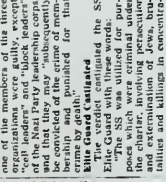
Exquisitely Styled Bridal Set \$125.00

ZALU
631 16th Street

Seven Firemen Get Promotions

Six firemen were raised to the rank of lieutenant by the city council last night.

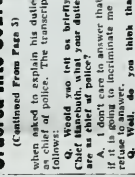
The promotions were: Joseph J. Kirschling, manager of the fire department; William J. Kirschling, assistant manager; Edward J. Kirschling, assistant manager; William J. Kirschling, assistant manager; Edward J. Kirschling, assistant manager; William J. Kirschling, assistant manager.



ARTHITIS RHEUMATISM

BICO TABLETS
Another Arthritis Product

Do you suffer from ARTHITIS or RHEUMATISM? Do you have stiff joints, swollen joints, or pain in the joints? Do you have difficulty in walking, or in climbing stairs, or in getting up and down? Do you have aching joints, or aching muscles, or aching bones? Do you have aching joints, or aching muscles, or aching bones? Do you have aching joints, or aching muscles, or aching bones?



Exquisitely Styled Bridal Set \$125.00

ZALU
631 16th Street

Tonight at Midnight!
 The new cartoon series "100% Pure" is now being shown in all theaters. It's a hilarious and exciting new series of short stories. Each episode is a new adventure. The characters are so funny and so full of life. You won't want to miss a single episode. It's the most exciting and funniest series ever shown. It's the new "100% Pure" cartoon series. It's the most exciting and funniest series ever shown. It's the new "100% Pure" cartoon series. It's the most exciting and funniest series ever shown.

Mrs. Rogers Pledges Last Ditch Fight Vets' Bills Given Good Chance in House
 WASHINGTON, Sept. 1 (AP)—Mrs. Rogers today pledged a last ditch fight to pass the veterans' bills through the House. She said the bills have a good chance of passing. The bills are the Veterans' Health Administration Act, the Veterans' Education Act, and the Veterans' Benefits Act. Mrs. Rogers said she would fight to the end to get these bills passed. She said she would not let the veterans down. She said she would fight to the end to get these bills passed. She said she would not let the veterans down.

Edith Wilson Candidate For Judge
 WASHINGTON, Sept. 1 (AP)—Edith Wilson, wife of Woodrow Wilson, is a candidate for the position of judge in the state of California. She is running for the position of judge in the state of California. She is running for the position of judge in the state of California. She is running for the position of judge in the state of California.

BLUE CROSS
 is by far the LARGEST VOLUNTARY HEALTH PLAN in the world.
 OVER 30 MILLION AMERICANS TRAVEL FIFTH PERSON IN THE UNITED STATES!
 • Hospital, hospital, and medical care • Life insurance • Dental • Health and accident insurance • Life insurance • Dental • Health and accident insurance

The Problems Of Auto Registration
 WASHINGTON, Sept. 1 (AP)—The problems of auto registration are being discussed in a report by the American Automobile Association. The report says that the current system is inefficient and costly. It suggests that a new system be implemented to streamline the process. The report says that the current system is inefficient and costly. It suggests that a new system be implemented to streamline the process.

Now! to the Capitol
 A 100% pure milk. It's the best milk in the world. It's the best milk in the world. It's the best milk in the world. It's the best milk in the world. It's the best milk in the world. It's the best milk in the world. It's the best milk in the world. It's the best milk in the world.

APPROVAL
 It is the greatest upgrade in popularity in Cadillac's eventful history—and a dice in great measure, to the public, term of thousands of people have placed their orders for these magnificent cars.

TRIOUBLED NEW SYMPTOMS OF ARTHRITIS? RHEUMATISM?
 The new medicine, Arthritis Relief, is the most effective treatment for arthritis and rheumatism. It works quickly and without pain. It is the most effective treatment for arthritis and rheumatism. It works quickly and without pain. It is the most effective treatment for arthritis and rheumatism. It works quickly and without pain.

Don Lee
 Since word of the new Cadillac was first heard by the public, term of thousands of people have placed their orders for these magnificent cars.

APPROVAL
 It is the greatest upgrade in popularity in Cadillac's eventful history—and a dice in great measure, to the public, term of thousands of people have placed their orders for these magnificent cars.

Diamonds Bought
 Buy diamonds from the world's largest diamond dealer. We have the best prices and the best quality. Buy diamonds from the world's largest diamond dealer. We have the best prices and the best quality. Buy diamonds from the world's largest diamond dealer. We have the best prices and the best quality.

TRIOUBLED NEW SYMPTOMS OF ARTHRITIS? RHEUMATISM?
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APPROVAL
 It is the greatest upgrade in popularity in Cadillac's eventful history—and a dice in great measure, to the public, term of thousands of people have placed their orders for these magnificent cars.



HEALTH FOODS
 113 Spring St. Boston, Mass. 02101
 Buy diamonds from the world's largest diamond dealer. We have the best prices and the best quality. Buy diamonds from the world's largest diamond dealer. We have the best prices and the best quality.

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 113 Spring St. Boston, Mass. 02101
 Buy diamonds from the world's largest diamond dealer. We have the best prices and the best quality. Buy diamonds from the world's largest diamond dealer. We have the best prices and the best quality.

EXHIBIT No. 3

[Title of District Court and Cause.]

Affidavit of Dr. Ronald M. Troup

United States of America,
Northern District of California—ss.

State of California,
County of Alameda

Before me, Ralph W. Weilerstein, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Dr. Ronald M. Troup in the County and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am a licensed physician in the State of California with a degree of Doctor of Medicine from the Southwest School of Medicine, Kansas City, Missouri. I am on the Medical Staff of the Hahnemann Hospital, San Francisco.

(2) I am currently President of both the San Francisco County Homeopathic Medical Society and of the California State Homeopathic Medical Society.

(3) I am engaged in the general practice of

medicine employing the principles of homeopathy in my practice.

(4) I have examined the labeling of a sample of Ri-co Tablets, the product currently under seizure in the Northern District of California, Civil Action No. 24872-H. The labeling declares the ingredients to be "Lithium Benzoicum, Ammonium Phos., Lycopodium."

(5) I have been asked by representatives of the United States Food and Drug Administration whether, in my opinion, these Ri-co Tablets would be therapeutically useful in the treatment or cure of arthritis or rheumatism or their symptoms according to the principles of homeopathy.

(6) At their request I have examined advertisement clippings from the Rocky Mountain News, Denver, Colorado, October 1, 1946, and the San Francisco Chronicle, June 7, 1948, which create the impression that these Ri-co Tablets are therapeutically useful in the treatment and cure of arthritis and rheumatism.

(7) In my opinion as a homeopathic physician, I feel that I would express the unanimous opinion of the homeopaths when I state that they would deplore the production and sale of this combination and its broad and indefinite diagnostic basis and that they would certainly deny acceptance of it as a prescription having either possibilities or worth.

(8) The statement "according to the principles of Homeopathy" it does thus and so is a blunt and plain untruth for no such combination was ever proven by the homeopaths. I am very certain that its use has been very limited and that at least close to one hundred per cent of homeopaths have not given it at all.

(9) The article is not homeopathic because homeopathy does not treat disease by name or diagnostic label. It is not homeopathic because according to the principles of homeopathy each of its ingredients establishes an individual symptom reaction and reversely in prescribing for illness the patient must exhibit symptoms that match the drug or there results no action or reaction returning that patient to health.

(10) In my opinion, it is the consensus of Homeopathic physicians that a lay person cannot use an article such as Ri-co efficaciously in the self-treatment of any disease because a lay person is not properly trained to make the detailed diagnosis which is required to differentiate between the indications for various homeopathic drugs.

/s/ RONALD M. TROUP.

Subscribed and sworn to before me at Berkeley this 27th day of August, 1948.

/s/ RALPH W. WEILERSTEIN,
Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

[Endorsed]: Filed Feb. 21, 1950.

EXHIBIT No. 4

Affidavit of Dr. Howard M. Engle

United States of America,
Northern District of California—ss.

State of California,
County of San Francisco

Before me, Ralph W. Weilerstein, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Dr. Howard M. Engle in the County and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am a specialist in the field of Internal Medicine and a graduate of the Hahnemann Medical College and Hospital of Philadelphia. I am chief of the Medical Staff of the Hahnemann Hospital, San Francisco.

(2) I have been engaged in the practice of medicine in the City of San Francisco since 1897. I am a Fellow of the American Medical Association. I have my offices at 450 Sutter Street in San Francisco. I have been trained in and daily practice the principles of Homeopathy in connection with my practice of medicine.

(3) I have examined the labeling of a sample

of Ri-co Tablets, the product currently under seizure in the Northern District of California, Civil Action No. 24872-H. The labeling declares the ingredients to be "Lithium Benzoicum, Ammonium Phos., Lycopodium."

(4) I have been asked by representatives of the United States Food and Drug Administration whether, in my opinion, these Ri-co Tablets would be therapeutically useful in the treatment or cure of arthritis or rheumatism or their symptoms according to the principles of homeopathy.

(5) At their request I have examined advertisement clippings from the Rocky Mountain News, Denver, Colorado, October 1, 1946, and the San Francisco Chronicle, June 7, 1948, which create the impression that these Ri-co Tablets are therapeutically useful in the treatment and cure of arthritis and rheumatism.

(6) In my opinion as a Homeopathic physician and a specialist in the treatment of chronic diseases, including arthritis, I may state that the statement in the advertising that this formula has stood the test of time and has been widely used by many Homeopathic physicians, is false since I have never heard of the combination of chemicals referred to nor have I heard of any Homeopathic physician who uses it. I would further state that the claim in the advertisement that "according to the principles of Homeopathy, improves the symptoms of muscular or ligamentous pain

and stiffness due to arthritis or rheumatism except when accompanied by a febrile condition'' is a complete misstatement of anything recognized as homeopathic practice.

(8) It is my opinion that this article cannot, according to the consensus of Homeopathic physicians, be used efficaciously in the self-treatment of a disease condition.

/s/ HOWARD M. ENGLE.

Subscribed and sworn to before me at San Francisco this 26th day of August, 1948.

/s/ RALPH W. WEILERSTEIN,
Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

[Endorsed]: Filed Feb. 21, 1950.

EXHIBIT No. 5

Affidavit of Dr. Frances Baker

United States of America,
Northern District of California—ss.

State of California,
County of San Francisco

Before me, Ralph W. Weilerstein, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security

Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Dr. Frances Baker in the County and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am a physician and surgeon with a degree of Doctor of Medicine licensed to practice in the State of California.

(2) I am Director of the Department of Physical Medicine at the University of California Hospital, San Francisco. I am Assistant Clinical Professor of Orthopedics at the University of California Medical School. I have been a member of the Arthritis Committee at the University of California Medical School, for over ten years. I have performed research in the field of arthritis and with respect to remedies offered for that disease. I regularly treat patients with arthritis daily and am thoroughly familiar with the disease conditions known as arthritis and rheumatism.

(3) I have examined the labeling of a sample of Ri-co Tablets, the product currently under seizure in the Northern District of California, Civil Action No. 24872-H. The labeling declares the ingredients to be "Lithium Benzoicum, Ammonium Phos., Lycopodium."

(4) I have examined advertisement clippings from the Rocky Mountain News, Denver, Colorado,

October 1, 1946, and the San Francisco Chronicle, June 7, 1948, which create the impression that these Ri-co Tablets are therapeutically useful in the treatment and cure of arthritis and rheumatism.

(5) In my opinion as a specialist in the treatment of arthritis these tablets would be of no value in the treatment or cure of arthritis or rheumatism nor in the relief of the symptoms of those disorders nor in improving the symptoms of muscular or ligamentous pain and stiffness due to arthritis or rheumatism whether or not accompanied by a febrile condition because these diseases and their symptoms are due to structural changes and functional changes in the bones, muscles, ligaments and joints which would not be affected by any of these ingredients.

(6) The ingredients above referred to are not considered by the consensus of medical experts nor by any physician whom I know as of any value in the treatment of arthritis or rheumatism or their symptoms.

/s/ FRANCES BAKER, M.D.

Subscribed and sworn to before me at San Francisco this 26th day of August, 1948.

/s/ RALPH W. WEILERSTEIN,
Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

[Endorsed]: Filed Feb. 21, 1950.

EXHIBIT No. 6

Affidavit of Dr. Windsor C. Cutting

United States of America,
Northern District of California—ss.

State of California,
County of San Francisco.

Before me, Ralph W. Weilerstein, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Dr. Windsor C. Cutting in the County and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am a Doctor of Medicine duly licensed to practice in the State of California. I am Professor of Therapeutics at the Stanford University Medical School in the Department of Pharmacology and Therapeutics.

(2) Therapeutics is the branch of medicine which has to do with the application of procedures and drugs in the treatment of disease conditions.

(3) I am the author of a book "Manual of Clinical Therapeutics" which has achieved nationwide acceptance and has been printed in several editions.

(4) I have examined the labeling of a sample of Ri-co Tablets, the product currently under seizure in the Northern District of California, Civil Action No. 24872-H. The labeling declares the ingredients to be "Lithium Benzoicum, Ammonium Phos., Lycopodium."

(5) I have examined advertisement clippings from the Rocky Mountain News, Denver, Colorado, October 1, 1946, and the San Francisco Chronicle, June 7, 1948, which create the impression that these Ri-co Tablets are therapeutically useful in the treatment and cure of arthritis and rheumatism.

(6) In my opinion as a specialist in therapeutics, the article Ri-co would be of no value in the treatment of arthritis or rheumatism or their symptoms because the article contains no ingredient which is of any recognized therapeutic value in the treatment of these diseases. The ingredients themselves have actions which are well known and none of which are recognized as of any value in the alleviation of the symptoms or the conditions of arthritis, rheumatism, muscular or ligamentous pain and stiffness with or without febrile conditions.

(7) In my opinion, it would be the consensus of experts in the field of therapeutics that the article Ri-co would be of no benefit for any of the conditions for which it is offered in the advertising clippings referred to above.

/s/ WINDSOR C. CUTTING,
Signature

Subscribed and sworn to before me at San Francisco this 26th day of August, 1948.

/s/ RALPH W. WEILERSTEIN,
Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

[Endorsed]: Filed Feb. 21, 1950.

[Title of District Court and Cause.]

CERTIFICATE OF CLERK TO
APOSTLES ON APPEAL

I, C. W. Calbreath, Clerk of the District Court of the United States for the Northern District of California, do hereby certify that the foregoing and accompanying documents and exhibits, listed below, are the originals filed in this Court, or true and correct copies of orders entered on the minutes of this Court, in the above-entitled case, and that they constitute the Apostles on Appeal herein, as designated by the Appellant, to wit:

Libel of Information.

Order for Warrant of Arrest and Writ of Monition.

Warrant of Arrest and Writ of Monition.

Stipulation for Change of Venue.

Order for Change of Venue.

Certificate of Clerk of the District Court of the United States for the District of Colorado as to certain papers.

Monition and Marshal's Return.

Claim of Owner.

Exceptions to Libel.

Order Overruling Claimant's Exceptions.

Answer to Libel.

Demand of Claimants and Respondents for Trial by Jury.

Motion for Summary Judgment.

Minute Order of November 10, 1949—Order that Motion for Summary Judgment Be Submitted and Continued for Decision.

Minute Order of November 16, 1949—Order that Motion for Summary Judgment Be Granted; Further Order that Claimant's Application For Leave To Salvage Seized Tablets For Relabeling Be Denied.

Findings of Fact and Conclusions of Law.

Decree of Condemnation and Destruction.

Petition for Appeal.

Order Allowing Appeal.

Notice of Appeal to the United States Court of Appeals for the Ninth Circuit.

Writ of Destruction.

Order Extending Time to Docket.

Citation on Appeal.

Designation of Errors and Statement of Points Relied Upon On Appeal.

Praeipce for Apostles On Appeal And Designation Of Portions Of Record, Proceedings And Evidence To Be Contained In Record on Appeal.

Reporter's Transcript for Wednesday, November

16, 1949—Decision On Motion For Summary Judgment.

Exhibits 1, 2, 3, 4, 5, 6, 7 and 8, attached to Brief in Support Of Motion For Summary Judgment, Filed October 15, 1948.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said District Court this 21st day of February, A.D. 1950.

C. W. CALBREATH,
Clerk,

[Seal] By /s/ M. E. VAN BUREN,
Deputy Clerk.

[Endorsed]: No. 12483. United States Court of Appeals for the Ninth Circuit. Alberty Food Products Co., a copartnership, consisting of Ada J. Alberty, Harry R. Alberty, Helen M. Alberty Hackworth, Kenneth J. Hackworth, Florence M. Alberty St. Clair and Margaret M. Alberty Quinn, Appellant, vs. United States of America, Appellee. Apostles on Appeal. Appeal from the United States District Court for the Northern District of California Southern Division.

Filed February 21, 1950.

/s/ PAUL P. O'BRIEN,
Clerk of the United States Court of Appeals for
the Ninth Circuit.

United States Court of Appeals
for the Ninth Circuit

No. 12483

UNITED STATES OF AMERICA,

Libelant and Appellee,

vs.

33 BOTTLES, MORE OR LESS, OF AN ARTICLE
LABELED IN PART "RI-CO TABLETS
HOMEOPATHIC COMBINATION
APP. 275 TABLETS"ALBERTY FOOD PRODUCTS CO., a Copartner-
ship Consisting of ADA J. ALBERTY,
HARRY R. ALBERTY, HELEN M. AL-
BERTY HACKWORTH, KENNETH J.
HACKWORTH, FLORENCE M. ALBERTY
ST. CLAIR and MARGARET M. ALBERTY
QUINN,

Claimant and Appellant.

APPELLANT'S STATEMENT OF POINTS
RELIED UPON ON APPEAL

Appellant hereby refers to points (1 to 5), inclusive, of its assignment of errors and statement of points relied upon on appeal heretofore filed with the Clerk of the District Court of the United States for the Northern District of California, Southern Division, and certified to the above entitled court by said Clerk as part of the record on appeal, and adopts the same as its statement of points relied

upon on appeal in accordance with the provisions of Rule 19, Subdivision 6, of the Rules of the above entitled court.

HAUERKEN, AMES &
ST. CLAIR

By /s/ GEORGE H. HAUERKEN,
Attorneys for Claimant
and Appellant.

Receipt of Copy attached.

[Endorsed]: Filed February 24, 1950.

[Title Court of Appeals and Cause.]

APPELLANT'S DESIGNATION OF PARTS
OF THE RECORD MATERIAL TO THE
CONSIDERATION OF THE APPEAL AND
TO BE PRINTED

Appellant hereby designates the following parts of the record certified to the above entitled court by the Clerk of the District Court of the United States for the Northern District of California, Southern Division, as the parts of the record material to the consideration of the appeal and to be printed:

(1) Libel of information (Record, Vol. 1, No. 1).

(2) Order for warrant of arrest and writ of monition (Record, Vol. 1, No. 2).

(3) Warrant of arrest and writ of monition (Record, Vol. 1, No. 3).

(4) Stipulation for change of venue (Record, Vol. 1, No. 4).

(5) Order for change of venue (Record, Vol. 1, No. 5).

(6) Monition and marshal's return (Record, Vol. 1, No. 9).

(7) Claim of owner (Record, Vol. 1, No. 10).

(8) Exceptions to libel, not including the memorandum of points and authorities in support of exceptions to libel (Record, Vol. 1, No. 15).

(9) Order overruling claimant's exceptions (Record, Vol. 1, No. 21).

(10) Answer to libel (Record, Vol 1, No. 24).

(11) Motion for summary judgment without any of the exhibits attached to the brief in support of the motion (Record, Vol. 1, No. 26).

(12) Minute order of November 10, 1949 (Record, Vol. 1, no No.).

(13) Minute order of November 16, 1949 (Record, Vol. 1, no No.).

(14) Findings of fact and conclusions of law (Record, Vol. 1, No. 32).

(15) Decree of condemnation and destruction (Record, Vol. 1, No. 33).

(16) Petition for appeal (Record, Vol. 1, No. 35).

(17) Order allowing appeal (Record, Vol. 1, No. 36).

(18) Notice of appeal (Record, Vol. 1, No. 37).

(19) Writ of destruction (Record, Vol. 1, No. 38).

(20) Order extending time to docket (Record, Vol. 1, No. 42).

(21) Citation on appeal (Record, Vol. 1, No. 43).

(22) Assignment of errors and statement of points relied upon on appeal (Record, Vol. 1, No. 44).

(23) Praecipe for apostles on appeal and designation of portions of record, proceedings, and evidence to be contained in record on appeal (Record, Vol. 1, No. 45).

(24) Certificate of the Clerk of the District Court of the United States for the Northern District of California, Southern Division, to apostles on appeal (Record, Vol. 1, no No.).

(25) Appellant's statement of points relied upon on appeal filed in the above entitled court.

(26) This designation.

HAUERKEN &
ST. CLAIR,

By /s/ GEORGE H. HAUERKEN,
Attorneys for Appellant.

Receipt of Copy attached.

[Endorsed]: Filed April 13, 1950.

[Title Court of Appeals and Cause.]

APPELLEE'S DESIGNATION OF ADDITIONAL PARTS OF THE RECORD MATERIAL TO THE APPEAL AND TO BE PRINTED

Appellee hereby designates the following parts of the record certified to this Court by the Clerk of the District Court of the United States for the Northern District of California, Southern Division, as additional parts of the record which are material to the consideration of this appeal and which should be printed:

(1) Demand of claimants for trial by jury. (Record, Vol. 1, No. 25.)

(2) Certain affidavits as listed below which are attached to the Government's Brief in Support of Motion for Summary Judgment, except that the brief itself is not to be printed. (Record, Vol. 1, No. 27.)

(a) Affidavit of McKay McKinnon, Jr., together with Exhibits A, B, and C attached thereto. (Ex. 2 of Brief.)

(b) Affidavit of Dr. Ronald M. Troup. (Ex. 3 of Brief.)

(c) Affidavit of Dr. Howard M. Engle. (Ex. 4 of Brief.)

(d) Affidavit of Dr. Frances Baker (Ex. 5 of Brief.)

(e) Affidavit of Dr. Windsor C. Cutting (Ex. 6 of Brief.)

(3) Reporter's transcript of proceedings on November 16, 1949. (Record, Vol. 2, No. 40.)

(4) This designation.

FRANK J. KENNESSY,
United States Attorney.

/s/ MACKLIN FLEMING,
Assistant United States
Attorney.

[Endorsed]: Filed April 18, 1950.

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No. 12,483

IN THE

**United States Court of Appeals
For the Ninth Circuit**

ALBERTY FOOD PRODUCTS Co., a copart-
nership consisting of ADA J. AL-
BERTY, HARRY R. ALBERTY, HELEN M.
ALBERTY HACKWORTH, KENNETH J.
HACKWORTH, FLORENCE M. ALBERTY
ST. CLAIR and MARGARET M. ALBERTY
QUINN,

Appellant,

vs.

UNITED STATES OF AMERICA,

Appellee.

APPELLANT'S OPENING BRIEF.

This is an appeal to the United States Court of Appeals for the Ninth Circuit from a decree in admiralty of the District Court of the United States for the Northern District of California, Southern Division, ordering the condemnation and destruction of a drug under the provisions of the Federal Food, Drug, and Cosmetic Act.

**JURISDICTION OF THE DISTRICT COURT AND OF THE
COURT OF APPEALS.**

This proceeding was begun in the District Court of the United States for the District of Colorado by the filing by the United States of a libel of information (Apostles on Appeal, p. 2) seeking the condemnation of 33 bottles of "Ri-Co Tablets" under the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U. S. Code, Sections 301 *et seq.*

The libel alleged that appellant Alberty Food Products Co. (hereinafter referred to as Alberty) shipped the Ri-Co Tablets, an article of drug, in interstate commerce from California to Colorado; that the tablets were then within the jurisdiction of the District Court for the District of Colorado; and that they were misbranded within the meaning of Section 352(f) (1) of the Act in that their labeling failed to bear adequate directions for use. The libel prayed for seizure, condemnation and disposition of the tablets in accordance with the provisions of the Act.

The tablets were seized by the U. S. Marshal for the District of Colorado. (Apostles on Appeal, p. 8.)

In accordance with the provisions of 21 U. S. Code, Section 334(a) Alberty and the United States thereafter stipulated to a change of venue from the District Court for the District of Colorado to the District Court for the Northern District of California, Southern Division (Apostles on Appeal, p. 9), and an appropriate order was made changing the venue to the District Court for the Northern District of California, Southern Division. (Apostles on Appeal, p. 11.)

After the filing by Alberty of a claim of owner (Apostles on Appeal, p. 14) and an answer denying that the tablets were misbranded as alleged in the libel (Apostles on Appeal, p. 18), the United States filed a motion for summary judgment. (Apostles on Appeal, p. 21.) The motion was granted and the decree of condemnation and destruction from which this appeal is taken was entered accordingly.

The appellate jurisdiction of this court rests upon 28 U. S. Code, Section 1291.

The decree of condemnation and destruction was entered on November 29, 1949. Alberty's petition for appeal and the order allowing the appeal were both filed on December 16, 1949. (Apostles on Appeal, pp. 33-34.) On the same day Alberty filed its notice of appeal, which notice had theretofore been served on the United States. (Apostles on Appeal, p. 34.)

After the docketing of the cause in this court, the United States filed a motion to dismiss the appeal on the ground that, the tablets having theretofore been destroyed by the U. S. Marshal pursuant to the decree of condemnation and destruction, the case had become moot. The motion was briefed and argued and was thereafter denied by this court without prejudice to its being renewed at the time of the hearing of the cause on the merits.

STATEMENT OF THE CASE.

Alberty is the manufacturer of Ri-Co Tablets, a homeopathic combination used for the relief of arthritis and rheumatism and sold in small bottles of approximately 275 tablets. (Apostles on Appeal, pp. 58-59.) Each bottle is labeled as follows:

(Front Panel)

Ri-Co

Tablets

Homeopathic

Combination

App. 275 Tablets

Each Tablet Contains:

Lithium Benzoicum

Ammonium Phos.

Lycopodium

Mfg. for and Packed by

Alberty Food Prod.

Hollywood, Calif.

(Side Panel)

Directions:

Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed.

(Side Panel)

Directions:

Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed.

(Apostles on Appeal, p. 57.)

The United States contends that that label does not bear "adequate directions for use" within the mean-

ing of Section 352(f) (1) of the Act, because it does not indicate the conditions for which the tablets are used, and that the tablets are therefore misbranded. In other words, the United States contends that the label of a drug cannot be said to bear adequate directions for its use within the meaning of the Act, even though it does indicate *how* the drug is to be used, unless the conditions for which the drug is to be used are also indicated on the label.

Alberty contends, however, that the requirement of "adequate directions for use" is fully complied with by directions on the label as to how the drug is to be used and that the Act does not require that the label include a statement of the conditions for which the drug is used.

In addition to that question of statutory construction, the question was also raised in the District Court of whether the summary judgment procedure provided by the Federal Rules of Civil Procedure is applicable in a condemnation proceeding under the Federal Food, Drug, and Cosmetic Act. It is Alberty's contention that, since the Act provides that the procedure in condemnation cases "shall conform, as nearly as may be, to the procedure in Admiralty" (21 U. S. Code, Section 334(b)), a summary judgment, which is of course unknown to the practice in Admiralty, cannot be rendered. The District Court rejected that contention, however, holding that the summary judgment procedure is applicable to a condemnation case under the Act as if such a proceeding were an ordinary civil case. The question of the cor-

rectness of that ruling of the District Court is also raised on this appeal.

Moreover, even assuming that a summary judgment is proper in a condemnation proceeding, Alberty contends that a summary judgment was improper in this proceeding, since a genuine issue of fact remains as to which Alberty is entitled to a jury trial.

Paragraph 4 of the libel raises the question of whether the directions given by Alberty for the use of the tablets are "adequate for its intelligent and effective use". It is Alberty's contention that the question of what is and what is not adequate for the intelligent and effective use of a drug is a question of fact as to which it is entitled to the determination of a jury.

Finally, the question was raised in the District Court of whether, assuming that the labeling of the tablets did not comply with the Act, the court should allow Alberty to re-label them. The court exercised its discretion against allowing the re-labeling of the tablets. That ruling, however, is not questioned on this appeal.

As part of its argument against re-labeling, the United States filed affidavits questioning the effectiveness of Ri-Co Tablets for the relief of arthritis and rheumatism, while, in support of its contention that re-labeling should be allowed, Alberty argued that a previous decision of the Federal Trade Commission authorizing it to use the proposed new label was in effect *res judicata* as to its right to re-label the tablets.

Neither the question of the effectiveness of the tablets nor the question of whether the ruling of the Commission was *res judicata*, however, is raised on this appeal. In the District Court, both questions were raised only in so far as they affected Alberty's right to re-label. Since that question of Alberty's right to re-label is not raised on this appeal, it follows that neither the question of the effectiveness of the tablets nor the question of the effect of the ruling of the Commission is now before this court. In fact, it must be noted that, even in passing upon the question of Alberty's right to re-label, the District Court did not rule on the effectiveness of the tablets. In its decision on the motion for summary judgment, the court stated:

"I am not holding that Ri-Co tablets are worthless. That issue actually was not presented to me." (Apostles on Appeal, p. 50.)

Similar language is found in the findings. (Apostles on Appeal, p. 28, Finding 15.)

It must also be noted that, although Alberty did not file affidavits supporting the effectiveness of Ri-Co Tablets for the relief of arthritis and rheumatism, it did not concede and does not concede that the tablets are not effective for the purposes for which they are used. Alberty fully expects to have to try the question, whether in this proceeding or in another proceeding, of the effectiveness of Ri-Co Tablets. Alberty accordingly chose not to disclose at this time the evidence upon which it intends to rely when the question

of the effectiveness of the tablets is tried. It may be that, had Alberty filed counter-affidavits, the District Court would have allowed the re-labeling of the tablets. The filing of counter-affidavits would have had no bearing on any other issue in the case, however, and, since that issue is now removed from the case, the fact that Alberty filed no counter-affidavits can have no bearing on this appeal.

With the exception therefore of the procedural issues of whether a summary judgment can be granted in a condemnation proceeding and whether a summary judgment should have been granted in this proceeding, the only issue before this court is the issue of whether the Act requires that the directions for the use of the tablets include a statement of the conditions for which they are used.

SPECIFICATIONS OF ERROR.

Assignments of error 1, 2, 3, 4 and 5 (Apostles on Appeal, p. 39) are relied upon by Alberty.

ARGUMENT.

(1) SPECIFICATIONS OF ERROR 4 AND 5.

Specifications of error 4 and 5 will be discussed first because they both relate to the procedural question of whether a summary judgment was proper in this case.

“(4) The court erred in deciding this case under rules applicable to civil cases instead of deciding it under rules applicable to admiralty

cases, and particularly in holding that the summary judgment procedure provided by rule 56 of the Federal Rules of Civil Procedure is applicable to a proceeding for the condemnation of a drug and in applying that procedure to this condemnation proceeding.

“(5) The court erred in finding and holding that no genuine issue as to any material fact remains unresolved with respect to the question of whether Ri-Co Tablets were misbranded; the court accordingly erred in granting the motion for summary judgment.”

Rule 56 of the Federal Rules of Civil Procedure provides that a summary judgment can be obtained by “a party seeking to recover upon a claim, counter-claim, or cross-claim or to obtain a declaratory judgment”. It is clear, under the very wording of the rule, that the United States was not entitled to a summary judgment for, in a condemnation proceeding, the United States is not in the position of “a party seeking to recover upon a claim, counter-claim, or cross-claim or to obtain a declaratory judgment”.

Even if the rule could be stretched so as to cover condemnation proceedings, it should not be so stretched, since the Food, Drug, and Cosmetic Act specifically provides that the procedure in condemnation cases “shall conform, *as nearly as may be*, to the procedure in admiralty.” (21 U. S. Code, Section 334(b), italics supplied.) To stretch Rule 56, a rule of *civil procedure*, so as to make it apply to condemnation cases would certainly not make the procedure

in such cases conform, *as nearly as may be*, to the procedure in admiralty.

Although the precise question of whether a motion for summary judgment can be made in a condemnation proceeding has not yet been passed upon, the following cases make it clear that admiralty practice should be adhered to at all stages of such a proceeding:

United States v. 149 Gift Packages, etc. (District Court E.D.N.Y., 1943), 52 F. Supp. 993. The court granted a motion to strike a counterclaim seeking a declaratory judgment on the ground that the legal sufficiency of a libel in a condemnation proceeding should be tested by exceptions and not by a counterclaim seeking a declaratory judgment.

United States v. 720 Bottles, etc. (District Court E.D.N.Y., 1944), 3 F.R.D. 466. The court held, *upon a motion of the United States*, that the provisions of the Federal Rules of Civil Procedure regarding the taking of depositions did not apply to condemnation proceedings under the Food, Drug and Cosmetic Act.

In any event, however, a summary judgment was improper, since this case presents a genuine issue of fact as to which Alberty is entitled to a jury trial. The pleadings raised the question of whether the directions given by Alberty for the use of the tablets are "adequate for its intelligent and effective use". The question of what is intelligent and effective like the question of what is reasonable is a question peculiarly within the province of a jury. Since such a question

of fact is thus presented in the case, summary judgment was improper.

Gifford v. Travelers Protective Ass'n. (C.C.A. 9, 1946), 153 Fed. (2d) 209;

Koepke v. Fontecchio (C.C.A. 9, 1949), 177 Fed. (2d) 125.

(2) SPECIFICATIONS OF ERROR 1, 2 AND 3.

Specifications 1, 2 and 3 will be discussed together because they all relate to the question of whether or not the act requires that the directions for the use of the tablets include a statement of the conditions for which the tablets are used.

“(1) The court erred in holding that Ri-Co Tablets were misbranded and in ordering their condemnation and destruction.

“(2) The court erred in finding and holding that the labeling of Ri-Co Tablets fails to bear adequate directions for use in that it does not declare the diseases or conditions of the body for which Ri-Co Tablets are offered to the public by appellant and for which appellant intends them to be used.

“(3) The court erred in finding that appellant ‘does not seriously contend that the Ri-Co Tablets are not misbranded as they are presently labeled’.”

Alberty is charged with a violation of Section 352(f)(1) of 21 U.S. Code. That section provides as follows:

“A drug or device shall be deemed to be misbranded—

“* * *

“(f) Unless its labeling bears (1) adequate directions for use; * * *”

It is apparent that Section 352(f)(1) does not in terms require the labeling of a drug to include a statement of the conditions or symptoms for which the drug is used. All that in terms is required is “adequate *directions for use*”. (Italics supplied.)

The Federal Food, Drug, and Cosmetic Act contains specific requirements as to what must be included on the label of a drug. The act leaves nothing to implication. In fact, as will hereinafter appear, the very section which Albery is alleged to have violated provides that, under certain circumstances, a label must indicate the conditions for which a drug should *not* be used. It is obvious, therefore, that when Congress intended that reference be made on a label to certain conditions, Congress knew how to specifically say so. Accordingly, the fact that Congress did not provide that every label should state the conditions *for* which the particular drug is used, must be taken to mean that Congress did not intend to make the lack of such statement misbranding under the Act.

Section 352 of the Act provides that a drug shall be deemed to be misbranded:

(1) “Unless its label states ‘the name and place of business of the manufacturer’.

(2) "Unless its label contains 'an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count'.

(3) "If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heron, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Administrator, after investigation, found to be, and by regulations designed as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement 'Warning—May be habit forming.'

(4) "If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2) in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of

this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator.

(5) "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement.

(6) "If it has been found by the Administrator to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Administrator shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Administrator shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(7) "If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

Congress was well aware that the label of a small bottle could contain only a limited amount of information. Yet, in addition to directions for use, it required information that could easily take up all the space available on the label. It is clear therefore that the words "adequate directions for use" must have been intended to refer only to a brief statement of the dosage (a statement which can easily be included within the limits of a label) and not to a detailed statement of all conditions or symptoms for which the drug is used (a statement which in many instances could not be included within the limits of the label).*

A short statement of how the drug is to be taken—how much, how often, in what manner, at what times, for how long—and how it is to be prepared for use, as for example a direction to "shake well before using", is all that is needed to make the use of the drug safe and effective. It cannot have been intended that the label should also contain a treatise on symptoms and conditions, yet, in many cases, a mere statement of symptoms or conditions would be misleading

*It is true that Section 352(f)(1) requires the directions for use to appear on the "labeling" of the drug and that Section 321(m) defines "labeling" as including the "label" on the immediate container and all other "accompanying" literature. This use of the more inclusive term "labeling" is nullified, however, by Section 352(c) which deems a drug misbranded unless all information required to appear on the labeling be placed thereon in such a manner as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. An attempt to place any of the required "directions for use" on accompanying literature would therefore be met by the contention that the ordinary purchaser customarily relies on the label itself and discards accompanying literature.

without a full explanation for which no space is available on the label.

That the Act does not contemplate that the diseases or conditions need appear on the labeling is made clear by its legislative history. A forerunner of the bill which finally passed provided that a drug would be misbranded if its labeling included the name of any disease for which it was not a cure but only a palliative and failed to state that the drug was a palliative and how the palliation was effected. Mr. W. G. Campbell, the then Commissioner of Food and Drugs, stated in discussing that provision (Senate Hearings on S. 2800, 73rd Congress, 2nd Session, p. 589) :

“Bear in mind that this paragraph applies *in those cases only where the name of a disease appears on the label.*” (Italics supplied.)

It is thus clear that, at that time, the Food and Drug Administration itself regarded the requirement of “adequate directions for use” as giving an option to the manufacturer to decide whether conditions for use should be stated on the labeling.

The intention of Congress is further shown by its rejection of the language of an earlier bill (S. 1944) which required that the labeling contain “complete and explicit” directions for use. Although that requirement went too far and Congress rejected it in favor of the lesser requirement of “adequate” directions for use, the Food and Drug Administration is now seeking to read it back into the Act.

It must also be remembered that we are dealing with criminal legislation. Although a condemnation

proceeding may not itself be a criminal proceeding, it results in the forfeiture of property and the same misbranding which forms the basis of a condemnation proceeding can be the basis of a criminal proceeding resulting in fine and imprisonment. (21 U. S. Code. Section 333.) The requirement of "adequate directions for use" must of course be given the same meaning in a condemnation proceeding as in a criminal proceeding. To construe those words to mean more than directions as to dosage, time and manner of taking a drug, would be to deprive Section 342(f)(1) of the clarity essential to the validity of a criminal statute. As stated in *Winters v. New York*, 333 U.S. 507, 515-516:

"The standards of certainty in statutes punishing for offenses is higher than those depending primarily upon civil sanction for enforcement. The crime 'must be defined with appropriate definiteness.' * * * There must be ascertainable standards of guilt. Men of common intelligence cannot be required to guess at the meaning of the enactment. The vagueness may be * * * in regard to the applicable tests to ascertain guilt."

A construction of the Act such as is advocated by the United States and was adopted by the District Court would accordingly result in depriving Albery of its property without due process of law. See for example *Conally v. General Construction Co.*, 296 U.S. 385, 391, where the court stated:

"A statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its

without a full explanation for which no space is available on the label.

That the Act does not contemplate that the diseases or conditions need appear on the labeling is made clear by its legislative history. A forerunner of the bill which finally passed provided that a drug would be misbranded if its labeling included the name of any disease for which it was not a cure but only a palliative and failed to state that the drug was a palliative and how the palliation was effected. Mr. W. G. Campbell, the then Commissioner of Food and Drugs, stated in discussing that provision (Senate Hearings on S. 2800, 73rd Congress, 2nd Session, p. 589):

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A construction of the Act such as is advocated by the United States and was adopted by the District Court would accordingly result in depriving Albery of its property without due process of law. See for example *Conally v. General Construction Co.*, 296 U.S. 385, 391, where the court stated:

"A statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its

meaning and differ as to its application, violates the first essential of due process of law.”

Since the penalty for failure to properly interpret the Act is forfeiture of property, fine and imprisonment, it should not be given the broad interpretation urged by the United States, for to do so would make it subject to grave constitutional doubts.

United States v. Delaware & Hudson Co., 213 U.S. 366, 407-8.

The very regulation which the Food and Drug Administration has issued as an interpretation of Section 352(f)(1) supports Albery's construction of that section. That regulation provides as follows:

“Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part * * * of * * * directions for use in all conditions for which such drug * * * is prescribed, recommended, or suggested in its labeling, or in its advertising * * * or in such other conditions, if any there be, for which such drug is commonly and effectively used; * * *” (21 Fed. Regs. (Cum. Supp.) Sec. 2.106(a).)

The most that can be said is that the regulation requires that adequate directions be given for the use of the drug in certain conditions. It does not require that the conditions themselves be stated on the label. If, for example, Ri-Co Tablets are prescribed and/or recommended and/or suggested and/or commonly and effectively used for two different conditions, the regulation, assuming it to be valid, would require that adequate directions be given on the label for their use

in one condition as well as in the other. It would be fully complied with, however, if the directions given on the label, as for example that Ri-Co Tablets be taken four times daily, were adequate for their use in both conditions. In other words, a direction that a drug be taken four times daily fully satisfies the requirement that adequate directions be given for the use of the drug in different conditions, provided the drug is to be taken four times daily in each of those conditions. Under such circumstances it would be highly unreasonable to require that the directions to take the drug four times daily be repeated on the label as many times as there are conditions for which the drug is prescribed, recommended, suggested or commonly and effectively used. In fact, the directions given on the label of Ri-Co Tablets are adequate for the use of those tablets in all conditions for which they are prescribed, recommended, suggested or commonly and effectively used.

If the Food and Drug Administration had intended to require that all conditions for which a drug is used be stated on the labeling of the drug, it would have done so by express language. Instead of doing so, however, it specified only that "directions for use" should be adequate for use in all conditions, whether it be a condition referred to in the labeling of the drug or in its advertising or a condition which is referred to neither in the labeling nor in the advertising, but for which the drug is nevertheless commonly and effectively used. In fact, the very use of the term "directions for use" as differentiated from the term "con-

ditions'' clearly demonstrates that the former is not intended to include the latter.

This case is one of first impression as far as an Appellate Court is concerned. There are a few recently decided District Court cases which appear to be in point and to support the position of the United States. They are of course not binding upon this court and, with all due respect to the courts deciding them, we believe them to be wrong. We will reserve discussing them in detail until we know which of them are relied upon by the United States. Most of them give no reasons in support of their conclusions and accordingly call for no discussion. At this point, we only wish to mention that all of those cases were decided after 1947. Since both the act and the regulations were adopted in 1938, it appears that the Food and Drug Administration itself did not interpret them as requiring a statement of conditions on the labeling until almost ten years after their adoption.

It seems to be the government's position that, unless the label discloses the conditions for which a drug is used, all sorts of misrepresentations can be made outside the label and dangerous drugs can be marketed with impunity. Nothing is further from the truth. The government is armed with all the weapons it needs to prevent misrepresentations made outside the label. If, for example, false and misleading statements are made in the advertising of Ri-Co Tablets, Alberty can be prosecuted under the Federal Trade Commission Act, 15 U. S. Code, Sections 41, *et seq.*, which, incidentally, give the Federal Trade Commission and not

the Food and Drug Administration jurisdiction over the false advertising of food, drugs, devices and cosmetics. And more specifically, if representations are made outside the label as to a condition for which the tablets may be used and the government finds that the directions given on the label are not adequate for their use in that condition, the government may *then* ask that the drug be condemned under the very provisions which it seeks to enforce by the present libel. Since, under our present system of government, the Food and Drug Administration is not entrusted with the task of writing a new and different law, it may not add an entirely new requirement to the requirements of the Act by the simple device of calling a statement of the conditions for which a drug is used, a statement of directions for its use.

Although it is not spelled out in the libel, one of the main objectives of the Food and Drug Administration is to force Alberty to include in the labeling of the tablets all of the representations that are made in their advertising. If the Food and Drug Administration were to achieve that objective, it could then indirectly control Alberty's advertising claims, in disregard of the express intention of Congress that control over advertising be left to the Federal Trade Commission.

To summarize: There is no contention in the libel and there can be no contention that Ri-Co Tablets are dangerous or detrimental when taken as directed on the label. In fact, there is no contention and there

can be no contention that the tablets are at all dangerous or detrimental. There is no contention in the libel and there can be no contention that the tablets should be taken otherwise than as directed on the label. In other words, those directions, "3 tablets with a cupful of hot water. Taken 4 times daily. Before meals and on going to bed." are adequate for their use.

Under the circumstances, this court should hold that the Act does not require the label to include a statement of the conditions for which the tablets are used and should accordingly reverse the decree with instructions to dismiss the libel. In the alternative, the decree should be reversed and the question of whether the directions are adequate for the intelligent and effective use of the tablets should be left to the determination of a jury.

Dated, San Francisco, California,

June 28, 1950.

Respectfully submitted,

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